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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

TRAVIS ITO-STONE, Individually and on behalf of all others similarly situated,

Plaintiff,

v.

DBV TECHNOLOGIES S.A., DANIEL TASSÉ, PIERRE-HENRI BENHAMOU, and DAVID SCHILANSKY, SUSANNA MESA

Defendants.

Case No. 2:19-cv-00525-MCA-LDW

SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

CLASS ACTION

Lead Plaintiffs Ruth Pruitt and Asdrubal Delgado ("Investors" or "Plaintiffs") individually and on behalf of all other persons similarly situated, by Investors' undersigned attorneys, for Investors' complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Investors' and Investors' own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Investors' attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding DBV Technologies S.A. ("DBV" or the "Company"), investigative interviews with former employees of the Company, consultation with an expert on issues concerning FDA approval, and review of other publicly available information concerning DBV. Investors believe that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased publicly traded American Depository Shares ("ADS") of DBV on the NASDAQ during the period from February 14, 2018 through March 16, 2020, inclusive (the "Class Period"). Investors seek to recover compensable damages caused by Defendants' violations

of the federal securities laws under Section 10(b) and 20(a) the Securities Exchange Act of 1934 (the "Exchange Act").

2. DBV is a clinical-stage specialty biopharmaceutical company developing an immunotherapy technology platform called Viaskin. DBV's lead product candidate is the Viaskin Peanut, a patch to be worn on the skin, designed to treat peanut allergies in children, adolescents and adults.

3. Defendants were in a race to become the first company to develop a United States Food and Drug Administration ("FDA") approved peanut allergy treatment, as there are no drugs or biologics on the market to treat peanut allergies.

4. The Viaskin Peanut patch must be approved by the FDA through the Biologics License Application ("BLA") process before it can be legally marketed and sold to the public.

5. On February 14, 2018, DBV announced that the FDA agreed that the available efficacy and safety data for Viaskin Peanut was sufficient to support the submission of a BLA.

6. The market responded exuberantly to DBV's long-awaited announcement that the FDA reacted favorably to safety and efficacy of the data as

supporting a BLA. After DBV's February 14, 2018 announcement the price of DBV's ADS traded at a whopping *nineteen times* the previous day's volume.

7. Thereafter throughout the Class Period, Defendants touted the Company's manufacturing process and assured investors that DBV was prepared to launch the Viaskin Peanut in 2019 based on its work "scaling up" and "refin[ing] our manufacturing process."

8. Unbeknownst to investors, however, DBV was experiencing serious problems with chemistry, manufacturing and controls ("CMC") and current good clinical practices ("cGMP") in connection with its electrospray technology. The electrospray manufacturing process, developed by DBV, was ***intended*** to spray homogenous, thin, dry protein layers onto the Viaskin patch. According to former employees of DBV, the electrospray technology had never been used by another company and there were intractable problems in scaling up such a technology for commercial production.

9. Additionally, the patch's design caused condensation to form on the patch such that the patch could not effectively adhere to the user's skin. Patch-site adhesion is critical to the patch working effectively. If the patch does not stick

properly to the skin, the active agent in the patch will not be delivered consistently and the patch will lose potency.

10. According to a former employee, DBV could not produce the Viaskin Peanut patch consistently and was having trouble controlling the exact 250mg dose that needed to be sprayed onto each Viaskin patch because the spray-jets became clogged when running at full production. In other words, DBV was unable to consistently produce the Viaskin Peanut product at optimal production levels needed for commercial production, and for approval of a BLA.

11. DBV was also unable to create a patch that did not fall off. When the patch was applied to the skin the patient's sweat would absorb the drug allergen in the patch. The sweat in turn caused condensation, leading to the patch falling off. Although the condensation caused adhesion problems, condensation was, in fact, a critical element of how the Viaskin product worked. In essence, it was by way of the condensation created by the patient's sweat that the drug allergen was absorbed by the patient. The patch itself created a "dome-like effect" which precipitated sweat from the patient and allowed the drug to be absorbed, but also led to the adhesion problems. In clinical studies, DBV attempted to remedy this problem by using Tegaderm, a hypoallergenic adhesive dressing to prevent the patch from falling off of the patient's skin. Early on, the FDA permitted DBV to use Tegaderm to "prevent possible patch adhesion issues." However, the FDA cancelled its decision to permit

DBV to use Tegaderm in connection with its clinical trials on February 2, 2017. Nevertheless, DBV continued to rely on Tegaderm to make the patch adhere.

12. Additionally, DBV was aware of the FDA's high pre-specified standard for demonstrating adhesion. According to the October 4, 2017 Statistical Analysis Plan for DBV's PEPITES Trial (which was not publicly available until February 22, 2019) for the clinical trial to be successful, the FDA would consider patch adhesion as acceptable only if 90% of the patches at the time of patch removal had an adhesion score of less than or equal to 1. A rating of "1" on the FDA's adhesion scoring system means that between 75 and 90% of the patch is still stuck to the skin and only some of the edges have lifted off.

13. In October 2017, DBV announced topline results from PEPITES showing a statistically significant response with a favorable tolerability profile. DBV knew, but failed to disclose to investors, that in the study Viaskin failed to meet the FDA's pre-specified adhesion requirement of 90%, casting serious doubt on its efficacy and making it highly unlikely the FDA would approve a BLA.

14. Despite these issues, Defendants forged on. Leading up to DBV's March 23, 2018 public offering – in which Defendants raised *$172.5 million* from investors – Defendants continued to tout Viaskin and its electrospray technology's

readiness to support DBV's BLA. As stated by Defendant Mesa, DBV's Chief Business Officer, on March 14, 2018 at Barclay's Global Healthcare Conference:

> It's an electrostatic patch. We have our own machine in-house that we've developed in order to not only formulate the antigen that goes in to the patch, but you spray it in a very unique manner, which is what allows Viaskin to deliver the antigen in the skin and not through the bloodstream.
>
> So we also have, aside from the clinical standpoint, some CMC requirements that need to be filed with the BLA filing as well. ***So all of those items will be ready in the second half this year, and that keeps us on track in terms of when we expect to get clinical approval*** and if the product is approved and when we would launch if the product is indeed approved.

15. October 22, 2018, DBV announced it had submitted a BLA to the FDA for Viaskin Peanut. The submission of the BLA triggered a 60-day review period during which the FDA would preliminarily assess the BLA to determine whether the BLA would be accepted for a full review, or whether the FDA would issue a refusal to file ("RTF") for the application.[1] Thus, the FDA's decision on the sufficiency of the BLA submission was due on December 21, 2018.

16. Surprisingly, shortly after DBV submitted its BLA for Viaskin Peanut—a product the Company had been working on for 10 years—on November

[1] An RTF is "refuse to file." When an NDA or BLA is deemed incomplete by the FDA it can decide not to review the application.

29, 2018, Defendant Pierre-Henri Benhamou, DBV's CEO and co-founder since 2002, resigned from the Company.

17. Following DBV's submission of the BLA, the Company continued to experience serious manufacturing complications threatening its BLA. As a result of these CMC problems, just days before the date set for the FDA to issue its decision on whether it would accept the BLA for filing, DBV withdrew the application to avoid receiving an RTF. On December 19, 2018, after the close of trading, the Company issued a press release announcing that its "BLA [for Viaskin Peanut was] withdrawn following discussions with the FDA regarding ***insufficient data on manufacturing procedures and quality controls***[.]"

18. Given the Company's repeated assurances about the adequacy and readiness of its manufacturing processes, DBV's announcement that it had withdrawn the BLA stunned the market. As a result of this news, the Company's share price plummeted, dropping $8.39 per share, from a closing price of $14.15 on December 19, 2018 to close at $5.76 on December 20, 2018—a one-day drop of nearly 60%.

19. Even though Defendants had not remedied the known problems with the patch, and impermissibly relied on Tegaderm to make the patch adhere to the skin and could not manufacture a patch that met the FDA's pre-specified adhesion

rate, they nevertheless forged ahead with seeking FDA approval of the Viaskin Peanut patch.

20. On February 13, 2019 the Company announced plans to resubmit its BLA application for the Viaskin Peanut patch in the third quarter of 2019. The Company's recently appointed CEO Daniel Tassé assured investors that the Company had "undertaken a comprehensive review of not only CMC issues but the entire BLA for resubmission." In response, DBV stock rose 11%.

21. Five weeks later, Defendants raised $81 million from investors in a public offering the Company announced on April 3, 2019.

22. Then, on August 7, 2019 Defendants announced the Company had resubmitted its BLA to the FDA. Defendants reassured investors that "the submission addresses the additional data needed on manufacturing procedures and

quality controls which were communicated by the FDA in December 2018, when DBV voluntarily withdrew its prior BLA submission for the Viaskin Peanut."

23. On October 4, 2019 Defendants announced the FDA accepted the Company's BLA for filing (not approval), prematurely implying the potential commercial launch date for the Viaskin Peanut patch in the second half of 2020.

24. On the heels of this positive news, Defendants raised an additional $125 million from investors in yet another public offering that closed on October 10, 2019.

25. Prior to the close of the Class Period Defendants were able to conduct yet another stock offering. On January 29, 2020 the Company launched a public offering that closed on February 4, 2020, raising $153.7 million from investors. In total, Defendants raised over half a billion dollars $*532.2 million* in Class Period stock offerings.

26. Indeed, the over half billion dollars Defendants raised during the Class Period was DBV's lifeblood, as DBV stated in its 2017 and 2018 20-F's that there was substantial doubt about the Company's ability to continue as a going concern given its lack of cash and failure to generate product revenue. DBV's financial condition was precarious and it desperately needed to raise money from investors in order to stay in business. This made the success of the Viaskin Peanut and DBV's

quest for FDA approval of it that much more critical, bringing DBV's assurances about the BLA's progress to the forefront of the investors' focus.

27. On February 21, 2020 the Company announced that an FDA Advisory Committee meeting to review Viaskin Peanut would take place on May 15, 2020. Defendant Tassé addressed the Company's earlier, December 2018, BLA withdrawal on a February 26, 2020 conference call, assuring investors that DBV rectified all issues concerning the BLA for Viaskin Peanut standing in the way of FDA approval. Tassé stated: "[w]e were first faced with the setback of a delay that we had to **pull and re-file.** *All that work was done***. The team did a fantastic job."**

28. Then, on March 16, 2020, the Company disclosed that the FDA had "identified questions regarding [Viaskin Peanut's] efficacy, including patch-site adhesion."

29. DBV would therefore have to submit additional information to the FDA that could constitute a major amendment to the BLA, and would result in a significant delay of FDA approval until DBV fixed the problem.

30. Given Defendants' repeated assurances that the Company had comprehensively reviewed the BLA and resolved all issues standing in the way of FDA approval of the Viaskin Peanut patch, this news stunned investors. This news caused the Company's share price to plummet $2.72 per share, from a closing price

of $5.26 per share on March 16, 2020, to open at $2.54 on March 17, 2020—a one-day drop of nearly 52%.

31. As a result of Defendants' misrepresentations and omissions about the adequacy of Viaskin Peanut's manufacturing process and quality controls and inability to produce a patch that met the FDA's prespecified adhesion criteria to support BLA approval, DBV's stock price has declined in value and Plaintiffs and other Class members have suffered significant losses and damages.

32. Defendants misled investors about the prospects for BLA approval of the Viaskin Peanut patch throughout the Class Period.

33. During the Class Period Defendants knew that: 1) DBV was incapable of manufacturing reproducible and consistent Viaskin Peanut patches because of problems with DBV's electrospray technology (i.e. the electrospray jets became clogged during production) and thus DBV had serious CMC and cGMP problems; 2) DBV could not produce a patch that adhered to the user's skin and failed to meet the FDA's prespecified adhesion criteria for the Phase III clinical trials, casting serious doubt on Viaskin Peanut patch's efficacy and making it highly unlikely that FDA would approve a BLA. Despite Defendants' knowledge of the foregoing they continued to mislead investors about the status of the Viaskin Peanut patch's

manufacturing readiness and the clinical trials' ability to successfully support a BLA.

II. JURISDICTION AND VENUE

34. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

35. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

36. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district, and the Company has operations and conducts substantial business in this district.

37. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail,

interstate telephone communications, and the facilities of the national securities exchange.

III. PARTIES

38. Lead Plaintiff Ruth Pruitt purchased DBV ADS at artificially inflated prices during the Class Period and has been damaged thereby. Her PSLRA certification was previously filed with this Court (Dkt. No. 5-5). Her updated PSLRA certification is attached hereto and is incorporated by reference herein.

39. Lead Plaintiff Asdrubal Delgado purchased DBV ADS at artificially inflated prices during the Class Period and has been damaged thereby. His PSLRA certification was previously filed with this Court (Dkt. No. 5-5). His updated PSLRA certification is attached hereto and is incorporated by reference herein.

40. Defendant DBV was incorporated in France in 2002. DBV's principal executive offices are in Montrouge, France. DBV is a clinical-stage specialty biopharmaceutical company focused on developing a novel immunotherapy technology platform called Viaskin. DBV's lead product candidate is the Viaskin Peanut, designed to treat peanut allergies in children, adolescents and adults. DBV also has offices in North America in New York, New York and Summit, New Jersey. DBV's Summit New Jersey office is a commercial facility intended to support the launch and commercialization of Viaskin Peanut in North America if

the appropriate regularly approvals are received. DBV ADS began trading on the NASDAQ Global Select Market ("NASDAQ") under the ticker symbol "DBVT" on October 22, 2014. DBV's ordinary shares have traded on the Euronext Paris Stock Exchange under the symbol "DBV" since its initial public offering in March 2012.

41. Defendant Daniel Tassé ("Tassé") has served as the Company's Chief Executive Officer ("CEO") since November 29, 2018.

42. Defendant Pierre-Henri Benhamou ("Benhamou") co-founded DBV Technologies in 2002. Benhamou served as the Company's CEO from 2002 until November 29, 2018. Prior to co-founding DBV, Benhamou was a physician in pediatric gastroenterology.

43. Defendant David Schilanksy ("Schilanksy") served as the Company's Deputy Chief Executive Officer (also known as the Principal Financial Officer) from December 2017 through May 16, 2019. Schilansky served as the Company's Chief Operating Officer ("COO") from January 2015 until December 2017.

44. Defendant Susanna Mesa ("Mesa") has served as the Company's Chief Business Officer ("CBO") from December 2017 through May 2019. Prior to

serving as the CBO, Mesa was the Company's Senior Vice President of Strategy from April 2016 to December 2017.

45. Defendants Tassé, Benhamou, Schilanksy, and Mesa are collectively referred to herein as the "Individual Defendants."

Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

46. DBV is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

47. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to DBV under *respondeat superior* and agency principles.

48. Defendants DBV and the Individual Defendants are collectively referred to herein as "Defendants."

IV. BACKGROUND

A. Company Background and the Viaskin Peanut

49. As a clinical stage biopharmaceutical company, DBV has not generated income from its operating activities and has incurred net losses each year since its inception in 2002. DBV has devoted most of its financial resources to research and development, including clinical and pre-clinical development activities. DBV has primarily funded its operations through the sale of equity securities.

50. DBV's lead product candidate is a patch worn on the skin called the Viaskin Peanut patch, designed to treat peanut allergies. The patch is designed to deliver peanut allergens in a controlled manner to stimulate immune intolerance.

For patients facing potentially life-threatening peanut allergies this treatment aims to desensitize them to allergens by delivering compounds in small quantities into the outer layers of the skin.

51. Indeed, there are currently no drugs or biologics on the market that treat peanut allergies. Treatment of peanut allergies is an important unmet need. According to a paper published in the Immunology and Allergy Clinics of North America, food allergies - mainly peanut allergies, are responsible for 150 to 200 deaths and about 200,000 emergency room visits every year in the United States. Peanut allergies are particularly difficult for young children to manage, and due to their life-threatening nature, can lead to psychological trauma and social anxiety. In some cases, these allergies can also cause chronic diseases such as failure to thrive in children and an allergic inflammatory condition of the esophagus called eosinophilic esophagitis, or EoE.

52. Given this critical unmet need—and major market opportunity—DBV was in a race to market - to be the first company to develop an FDA approved peanut allergy treatment, competing against rival company Aimmune Therapeutics, Inc., which is also developing a peanut allergy treatment consisting of a formulation of peanut flour for oral administration intended for oral desensitization to peanut. The

untapped market for peanut allergy treatment is expected to grow to $4.5 billion globally by 2027.

53. DBV describes itself as "focused on changing the field of immunotherapy by developing a novel technology platform called Viaskin." DBV's therapeutic approach is based on epicutaneous immunotherapy, or "EPIT," its proprietary method of delivering biologically active compounds to the immune system through intact skin using Viaskin. DBV's proprietary platform is its epicutaneous Viaskin patch. DBV designed and developed this technology internally, representing that it had "scalable manufacturing capabilities."

54. Viaskin is an electrostatic patch that DBV describes as offering a "convenient, self-administered, non-invasive immunotherapy to patients." The process, fully developed by DBV, uses an electrospray to spray homogenous, thin, dry protein layers onto the Viaskin patch. This process sprays a liquid solution of electrically charged proteins onto the patch's backing, that is then turned into a dry solid charged particle, that remains stuck into the patch's backing. It deposits very small and precise quantities of the active substance, devoid of adjuvants. The patch can then by stored at room temperature, providing a long shelf life. When Viaskin is applied on intact skin it forms a condensation chamber that hydrates the skin and solubilizes (dissolves) the antigen, allowing it to penetrate the epidermis, where it is captured by cells. This mechanism is designed to generate an immune response

that results in allergen desensitization. Desensitization consists of repeated administration of small quantities of allergen to decrease allergen reactivity in patients.

55. According to DBV the key elements of the Viaskin patch mechanism of action are the following: 1) a dry layer of allergen in its center, the patch is positioned on intact skin, without prior preparation; 2) the condensation chamber formed between the skin and the center of the patch creates hyperhydration of the skin and an accumulation of water; 3) the accumulation of water solubilizes the allergen. This condensation chamber makes the epidermis more permeable allowing the allergen to pass into the epidermis; and 4) once on the epidermis, the allergen is captured by a population of highly specialized cells: Langerhans cells. These cells can take the protein at the surface of the skin, process it and present its epitopes to the lymphocytes in the lymph nodes.

56. DBV believes that EPIT is a preferred method of desensitization compared to other desensitization methods, such as subcutaneous, sublingual and oral immunotherapy, that often require frequent or prolonged administration in specialized centers. These methods are considered poorly designed for pediatric patients due to their safety profile and method of administration. Some of these approaches are also known for triggering severe adverse events related to treatment, including anaphylaxis, risking the patient's life. Accordingly, DBV believes that

Viaskin has positioned DBV as the company with the most advanced clinical program in food allergies to date.

57. DBV "do[es] not expect to generate material revenue from product sales unless and until [it] successfully complete[s] development of, and obtain[s] marketing approval for, one of more of [its] products. DBV has operated at a loss since its inception and has "primarily funded these losses through equity financings." It, "has no product revenue and management expects operating losses to continue for the foreseeable future." During the Class Period DBV warned investors that "there are material uncertainties regarding our ability to continue as a going concern."

B. Expert Dr. Philip Lavin

58. Prior to filing the Second Amended Complaint, Plaintiffs engaged Dr. Philip Lavin, a clinical trial, biostatistics and FDA regulatory expert. Dr. Lavin has provided Plaintiffs with scientific and regulatory advice and guidance and an opinion as to Defendants' Class Period statements.

59. Dr. Lavin is the Principal of Lavin Consulting LLC. In this capacity Dr. Lavin serves as an independent biostatistical consultant and strategic planner

for clinical trial design, conduct, analysis, execution, and representation to regulatory and reimbursement agencies.

60. Dr. Lavin has served as the Lead Biostatistician for 66 regulatory approvals. He has been doing so for over 40 years.

61. Dr. Lavin has published nearly 200 peer-reviewed publications. He is the only person to be an elected fellow of both the American Statistical Association and the Regulatory Affairs Professional Society. Dr. Lavin's resume is attached as Exhibit 1 to this Complaint.

62. Dr. Lavin reviewed the published PEPITES trial data and the portions of DBV's SEC filings and investor conference call transcripts that are relevant to this action.

63. Dr. Lavin's expert opinion is included in relevant portions below.

C. The FDA Approval Process

64. In the United States the FDA regulates biologics under the Federal Food, Drug and Cosmetic Act, or FDCA.

65. The Viaskin Peanut patch must be approved by the FDA through the Biologics License Application, BLA, process before it can be legally marketed.

66. As DBV stated in its 2017 Form 20-F filed with the SEC on March 16, 2018 ("2017 20-F") the FDA process for a biologic to be marketed in the U.S. generally involves the following:

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, pre-clinical animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;

- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed product candidate for its proposed indication;

- submission to the FDA of a BLA;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the product is produced to assess compliance with the FDA's current good manufacturing practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;

- potential FDA audit of the pre-clinical and/or clinical trial sites that generated the data in support of the BLA; and

- FDA review and approval of the BLA prior to any commercial marketing or sale of the product in the United States.

67. The data necessary to support a BLA is generated in two distinct stages: pre-clinical and clinical. The pre-clinical development stage generally involves laboratory evaluations of drug chemistry, formulation and stability, as well as studies to evaluate toxicity in animals, which support subsequent clinical testing. The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators.

68. Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase I, Phase II and Phase III clinical trials. Phase III clinical trials generally involve large numbers of patients at multiple sites, in multiple countries (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the efficacy of the product for its intended use, its safety in use, and to establish the overall benefit/risk relationship of the product and provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase III clinical trials are required by the FDA for approval of a BLA.

69. Following trial completion, trial data is analyzed to assess safety and efficacy. The results of pre-clinical studies and clinical trials are then submitted to

the FDA as part of a BLA, along with proposed labeling for the product and information about the manufacturing process and facilities that will be used to ensure product quality, results of analytical testing conducted on the chemistry of the product candidate, and other relevant information.

70. The BLA is a request for approval to market the biologic for one or more specified indications and must contain proof of safety, purity, potency and efficacy, which is demonstrated by extensive pre-clinical and clinical testing.

71. After the BLA submission is accepted for filing, the FDA reviews the BLA to determine, among other things, whether the proposed product candidate is safe and effective for its intended use, and whether the product candidate is being manufactured in accordance with "Current Good Manufacturing Practice" or "cGMP" to assure and preserve the product candidate's identity, strength, quality, purity and potency.

72. Before approving a BLA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with

cGMP requirements and adequate to assure consistent production of the product within required specifications.

73. After the FDA evaluates the application, manufacturing process and manufacturing facilities, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase III clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, pre-clinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

C. cGMP and CMC

74. Part 211 of Title 21 of the Code of Federal Regulations ("CFR") sets for Current Good Manufacturing Practice for Finished Pharmaceuticals (i.e. cGMP). Part 211 contains twelve subparts, A-K, each of which have various subsections. These detailed regulations alert manufacturers as to the requirements concerning: buildings and facilities, organization and personnel, equipment, control

of components and drug product containers and closures, production and process controls, packaging and labeling control, holding and distribution, laboratory controls, records and reports and returned and salvaged drug products. In other words, GMPs cover all aspects of production- from the materials, premises and equipment to the qualifications, training and cleanliness standards of staff and management. Detailed written procedures are essential for the quality of a finished product. A manufacturer must establish specific recordkeeping instructions demonstrating that procedures are consistently and correctly followed at each step in the manufacturing process, each time a product is made.[2]

75. The goals of cGMPs are to ensure that the marketed product is the same or similar to the product demonstrated to be safe and effective in the clinical safety and effectiveness studies; to ensure that the manufacturing process consistently yields a product meeting approved quality attributes; and to ensure that the product will maintain its quality attributes throughout its shelf life. *Id.*

76. CMC refers to Chemistry, Manufacturing and Controls. CMC review and cGMP compliance may overlap but are not the same. GMPs relate to quality systems, overall operation and is facility oriented. CMC is product specific and

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[2] *See* "Chemistry, Manufacturing and Controls (CMC) and Good Manufacturing Practices (GMPs): The Big Picture of a Long-term Commitment," Elizabeth Pollina Cormier, Ph.D., Review Chemist Division of Manufacturing Technologies FDA/CVM/ONADE, available at: www.accessdata.fda.gov>static>cvm>cormier>CMCsandCGMPS.

relates to understanding process. *Id.* The critical elements of CMC look at: How and where the drug is made, how raw materials are tested and monitored, what control procedures are in place to assure product consistency and quality, whether quality attributes are adequately identified and characterized for the product, whether test methods to use product quality are appropriate and how long the product maintains its quality after it is made. *Id.*

77. CMC exists to assure that the drug sold to the public will have quality attributes similar to those of the drug demonstrated to be safe and effective; to assure that the quality of the drug meets appropriate standards and is consistent; and to assure that the drug is the same drug as described on the label. *Id.* In short, CMC helps maintain the connection in quality between the drug used in the clinical studies and the drug to be marketed to consumers. *Id.* For example, a manufacturing process under control will exhibit consistency of product quality with low variability between different batches of the product. *Id.*

78. The bottom line is that through ensuring CMC and cGMP compliance, manufacturers ensure that quality is designed into the manufacturing process itself and that quality is maintained as long as the product is marketed.

D. Adhesion with Transdermal and Topical Delivery Systems

79. As Dr. Lavin explains, the Viaskin Peanut patch's ability to consistently and reliably adhere to the patient's skin is critical. Indeed, adhesion is the *sine que non* of any transdermal delivery system ("TDS").

80. Transdermal and topical delivery systems, like the Viaskin Peanut patch must demonstrate a prespecified adhesion rate for the FDA to deem it effective and to pass FDA scrutiny.

81. In October 2018 the FDA's Center for Drug Evaluation and Research (CDER) published a Guidance for Industry ("Guidance") entitled "Assessing Adhesion with Transdermal and Topical Delivery Systems for ANDAs".

82. According to Dr. Lavin, the FDA has considerable experience with transdermal patches that deliver medications through the skin. The amount of drug delivered into and through the patient's skin from a TDS is dependent, in part, on the surface area dosed. For Viaskin, DBV dosed the surface area of the patch by electrospraying it with antigen proteins. To be effective, the patch must reliably adhere to the skin in order to build up sufficient moisture as the moisture enables the antigen to be absorbed through the skin. It is therefore mandatory that the entire contact surface area of a TDS remain consistently and uniformly adhered to the

patient's skin throughout the duration of wear under the conditions of use included in the product labeling.

83. As Dr. Lavin explains, when a TDS loses its adherence during wear, the amount of drug delivered to the patient may be reduced. During the product's labeled wear period, a TDS is reasonably expected to encounter torsional strains arising from body movements, changes in environmental temperature or humidity such as the daily exposure to water (e.g., during routine showering), and contact with clothing, bedding or other surfaces. TDS products that do not maintain consistent and uniform adhesion with the skin during the labeled wear period can experience varying degrees of TDS detachment which undermine efficacy, including complete detachment, at different times during the product wear. When the adhesion characteristics of a TDS are not sufficiently uniform (as governed by pre-defined adhesion specifications**)**, as evaluated against its labeled conditions of use, the TDS may exhibit variability in the surface area that is in contact with the skin. For example, when a TDS is partially detached, there may be uncertainty about the resulting drug delivery and, hence, uncertainty about the rate and extent of drug absorption from the TDS. When the potential for complete detachment of the TDS increases, the risk of unintentional exposure of the drug product to an

unintended recipient (e.g., a chemically sensitive household member who may be a child) also increases.[3]

84. Manufacturers of transdermal delivery systems, like DBV, are required to conduct adhesion studies. The Guidance states that "applicants should not use an overlay or cover for blinding because the overlay or cover may affect the product's performance." In other words, the product must adhere to the patient's skin on its own and not have to depend on extraneous adhesives.

85. To assess adhesion, the Guidance provides a five-point adhesion scale as follows: 0 = greater than or equal to 90% adhered (i.e., the TDS has essentially no lift off the skin); 1 = greater than or equal to between 75 to < 90% adhered (e.g., only some edges of TDS lift off the skin); 2 = greater than or equal to 50% to <75% adhered (i.e., less than half of the TDS lifts off the skin); 3 = > 0% to <50% adhered (i.e., the TDS is not detached, but more than half of it lifts off the skin without

[3] The Guidance states: "the amount of drug delivered into and through the patient's skin from a TDS (transdermal delivery system) is dependent, in part, on the surface area dosed. *It is expected that the entire contact surface area of a TDS should remain consistently and uniformly adhered to the patient's skin throughout the duration and wear under the conditions of use included in the product labeling. When a TDS loses its adherence during wear, the amount of drug delivered to the patient may be reduced*."

falling off); 4 = 0% adhered (i.e., the TDS is detached and is completely off the skin).

86. As Dr. Lavin explains, adhesion relates to CMC and cGMP as well as to safety and efficacy. DBV uses a passive delivery system for the Viaskin Peanut patch. A passive delivery system is any system that uses only non-facilitated flux to deliver drug to the stratum corneum (i.e. the outer layer of the skin); that is, they exclude facilitated systems involving physical approaches such as mechanical force, electrical force, pressure, radiation, heat, and sound. Since 1997, Scale-Up and Post Approval *C*hange (SUPAC) guidelines have governed passive delivery systems like the Viaskin Peanut patch. There are strict regulatory requirements to present comprehensive Chemistry, Manufacturing and Controls (CMC) information to the USA and international regulatory bodies involved in the review of the TDS dossier. Manufacturers use specific tools and approaches to achieve robustness of the finished TDS and to minimize or prevent unintended drift in the quality of the commercial drug product. These include process analytical technologies (PAT), quality by design (QbD), *in vitro–in vivo* correlation (IVIVC) and excipient characterization. These tools and approaches support both CMC and cGMP and are intertwined. Guidelines have been in place since 1997 from the Transdermal Dosage Form Workshop that follows the established SUPAC format of discussing the impact of (1) formulation or compositional changes, (2) process variable

changes, (3) process scale changes, and (4) process site changes on the finished quality parameters of the transdermal products. Thus, the TDS must undergo compliance and performance testing that FDA requires as part of the CMC submission in order to grant BLA approval.[4]

87. As Defendant Tassé admitted, the FDA required DBV to demonstrate that the Viaskin Peanut patch had an adhesion rate of 90% or greater: "*So the adhesion rate that was prespecified by the FDA based on their transdermal patch experience was that 90% adhesion rate was required.*"

88. According to Dr. Lavin, manufacturers are aware that if they fail to meet the adhesion performance specification set forth in the FDA guidance document and confirmed in the SAP, the FDA is highly unlikely to approve their product.

E. DBV has been Developing the Viaskin Peanut for over 10 years.

89. The Viaskin peanut received "Breakthrough" and "fast track designation" from the FDA in 2015 and 2012, respectively. A breakthrough therapy

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[4] Buskirk and Arsulowicz, et. al., *Passive Transdermal Systems Whitepaper Incorporating Current Chemistry, Manufacturing and Controls (CMC) Development Principles* AAPS PharmSciTech. 2012 Mar; 13(1): 218–230. Published online 2012 Jan 4. doi: 10.1208/s12249-011-9740-9 PMCID: PMC3279638; PMID: 22215291

is defined as a product that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. A breakthrough therapy designation affords the possibility of rolling review, enabling the agency to review portions of the marketing application before submission of a complete application, and priority review if supported by clinical data at the time of our BLA submission. "Fast track" designation means a product may have a faster development process. A manufacturer can apply for "fast track" designation where the product is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition.

90. In September 2014, DBV announced topline results for its Viaskin Peanut's Efficacy and Safety, or VIPES, Phase IIb clinical trial of Viaskin Peanut for the treatment of peanut allergic patients.

91. In October 2016, DBV announced topline results from the two-year OLFUS-VIPES Phase IIb study evaluating the long-term efficacy and safety

profile of Viaskin Peanut for the treatment of peanut allergic children. OLFUS-VIPES, or OLFUS, is an open-label, follow-up study to VIPES.

92. Following results from the Phase IIb programs above, DBV launched a Phase III program designed to assess the efficacy and safety of Viaskin Peanut in children. As part of its Phase III program development, DBV initiated the Peanut EPIT Efficacy and Safety Study, or PEPITES, a pivotal Phase III trial, in December 2015. PEPITES was designed to evaluate the safety and efficacy of Viaskin Peanut 250 µg in 356 peanut allergic patients four to 11 years of age.

93. In August 2016, DBV launched the REAL Life Use and Safety of EPIT (REALISE) study, which was designed to evaluate the use and safety of Viaskin Peanut 250 µg in routine clinical practice in 393 peanut allergic patients four to 11 years of age.

94. In August 2017, DBV initiated the EPIT in Toddlers with Peanut Allergy, or EPITOPE, a Phase III clinical trial assessing the safety and efficacy of Viaskin Peanut for the treatment of peanut allergic patients one to three years of age.

95. In October 2017, DBV announced topline results from PEPITES showing a statistically significant response with a favorable tolerability profile, with 35.3% of patients responding to Viaskin Peanut 250 µg after 12 months of treatment as compared to 13.6% of patients in the placebo arm (difference in response rates =

21.7%; p=0.00001; 95% CI = 12.4% - 29.8%). The study failed to achieve its primary endpoint of showing a statistically significant difference in response rates between the active and placebo arms as required by the Statistical Analysis Plan DBV submitted to the FDA.

96. In November 2017, DBV announced topline safety results from REALISE and that the trial met its primary objective. DBV claimed the trial showed that Viaskin Peanut was well-tolerated with no new or unexpected adverse events.

97. On February 14, 2018, DBV announced that the FDA agreed that the available efficacy and safety data for Viaskin Peanut supports the submission of a BLA, for the treatment of peanut allergy in children four to 11 years of age. The results from the PEPTITES and REALISE studies formed DBV's two Phase III trials necessary to support its BLA submission to the FDA. The FDA provided written responses to the clinical pre-BLA meeting package DBV submitted. These responses reflect agreement on the content of the clinical module of the BLA for Viaskin Peanut.

98. The Statistical Analysis Plan V4.0 for the PEPITES study ("SAP") describes the statistical methods to be used for the analyzing and reporting of data collected under the DBV Technologies Phase III protocol PEPITES. In other

words, the SAP represents the agreement between DBV and the FDA on the protocol for the statistical analyses of the PEPITES Study.

99. DBV did not make the SAP publicly available until February 22, 2019, the date DBV published the full results of the PEPITES study. The SAP is marked "CONFIDENTIAL" with an effective date of September 28, 2016 and a "Project Document Effective Date" of October 4, 2017.

100. The SAP, Section 4.11 entitled "Adhesion" sets forth the FDA's prespecified requirements that the Viaskin Peanut patch had to show to demonstrate adhesion:

> The viaskin patch adhesion will be evaluated during 28 days between M3 and M6…The scoring system for adhesion and occlusion of Viaskin patches is indicated as follows:..
> …Patch adhesion will be considered as acceptable if more than 90% of the patches at the expected time of patch removal, i.e. at 24 plus or minus 4 hours after patch application have an adhesion score of less than or equal to 1 as assessed by the subjects' parents/guardians. In other words, adhesion of the patch will be considered as acceptable if less than 10% of the patches are evaluated with an adhesion grade 2 or 3 at time of removal, during the period of adhesion, for the overall population.

101. According to Dr. Lavin, it is highly unlikely that the FDA would waive the pre-specified adhesion requirement set forth in the SAP. This is because an SAP is written to prevent ambiguity in the analyses to be conducted and the corresponding success criteria. In other words, if the PEPITES Study did not

demonstrate that the Viaskin Peanut patch met the adhesion standard set forth in the SAP it is highly unlikely the FDA would approve it.

102. Section 4.11 of the SAP also states that DBV is prohibited from using Tegaderm to make the patch stick to the user's skin:

> TEGADERM:
> "The use of hypoallergenic adhesive dressing (e.g. Tegaderm) to prevent possible patch adhesion issues was authorized on Dec. 2. 2016…and is collected in the eCRF (investigator assessment at study visits). ***Following a comment from the FDA, this decision was cancelled on Feb. 2, 2017.***

103. Given the date and content of the SAP, Defendants were already aware of the FDA's prespecified adhesion criteria and prohibition on the use of Tegaderm by no later than February 2, 2017.

V. DEFENDANTS MISLEAD INVESTORS CONCERNING DBV'S BLA FOR VIASKIN PEANUT

104. As noted above, in order to receive FDA approval, a biologic must not only be demonstrated to be safe and effective as proven through data from clinical trials, manufacturing of the product must comport with cGMP and CMC. Indeed, throughout the Class Period Defendants acknowledged the importance of CMC and cGMP for a product like the Viaskin Peanut.

105. Unbeknownst to investors, however, prior to, and during the heart of the Class Period, DBV was experiencing CMC and cGMP problems with its

electrospray technology. The electrospray manufacturing process, fully developed by DBV, was ***intended*** to spray homogenous, thin, dry protein layers onto the Viaskin patch. According to former DBV employees, the electrospray technology had never been used by another company and there were significant problems in scaling up the technology for producing large batches in commercial production, a necessity for DBV to obtain the FDA's approval of the BLA.

A. Confidential Witnesses Describe Serious Manufacturing and CMC Problems of Viaskin Peanut

106. Confidential Witness 1 ("CW1"), a Regional Director of Supply Chain from October 2016 to August 2017, traveled to DBV's manufacturing facility in France in the course of CW1's job duties. CW1 recalled that DBV was significantly behind in scaling up its Viaskin Peanut manufacturing operations to launch a commercial product. Based on what CW1 saw during this visit, CW1 said that although the Company had certain elements in place, such as financing, the Company had "a long way to go" in regard to scaling up the manufacturing processes.

107. CW1 stated that the Viaskin Peanut product represented "challenging" technology. As CW1 explained, the Viaskin Peanut product entailed atomizing a biologic agent into a substrate (*i.e.*, a liquid solution of electrically charged protein is sprayed onto the patch's backing, which turns into a dry solid charged particle). CW1 noted that the electrospray had the potential to be an "amazing" technology,

but based on what CW1 saw during the visit to France, the technology was "not scaled up" for commercial production. In short, while DBV could produce small batches for the Phase 3 trials, the technology was inadequate to produce the large-scale batches required for commercial production and FDA approval.

108. CW1 further reported that DBV was also experiencing a significant problem with the stability of the Viaskin Peanut patch. CW1 recalled that the Viaskin patches had been designed in such a way that it would fall off during the clinical trials. CW1 noted that this may have reflected a poor product design. According to CW1, a flat patch would have limited condensation between the under-layer of the patch and the skin, but the patch DBV was using at the time was ring-shaped in order to create the condensation required to cause the substrate and the peanut protein to go into action and be absorbed through the skin. The condensation, while necessary for the antigen protein to pass through the skin, unfortunately caused the patch to fall off of patients. Product stability is also required for FDA approval.[5]

[5] *See*, *e.g.*, FDA guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/q5c-quality-biotechnological-products-stability-testing-biotechnologicalbiological-products.

Moreover, if the patch falls off, the antigen is not delivered through the skin to the patient and the treatment is not effective.

109. CW1 stated that he recalls learning of the patch's adhesion problems through Pascale Ehouran, DBV's Vice President of Manufacturing. CW1 stated that he spent time with Ehouran in France, during his visit to DBV's manufacturing facility. Ehouran was responsible for developing the technology for manufacturing the Viaskin Peanut patches. This included the mechanism for electrospraying the relevant protein onto the patches. Accordingly, CW1 believes that Ehouran selected the adhesive material for the patches. CW1 explained that what occurred in DBV's manufacturing facility in France, including comments Ehouran made, was "very confidential." CW1 went on to state that Ehouran told him about the Viaskin Peanut patch's adhesion problems.

110. CW1 stated that based on informal conversations with employees at the manufacturing facility in France concerning the patch's adhesion problems, he ascertained upwards of 10%-20% of all patches DBV applied to patients in the clinical trials were having adhesion problems. Some of the employees CW1 recalls speaking with while in France are Ehouran, and Valerie Larricq, Vice President of Supply Chain Management at DBV in Fournay-sur-Marne, Ile-de-France. CW1 attributes this adhesion problem to a fundamental design flaw, because DBV

designed the patches to promote condensation necessary to promote absorption of the antigen through the skin.

111. CW1 explained that he did not believe DBV would consider using a different adhesive because such a change would have to be formally documented.in the clinical trial and the FDA would have to approve the change.

112. As Dr. Lavin explains, in order to use a different adhesive, DBV would have to find a solution within the 180-day review clock. DBV would not only have to find a better adhesive but would also have to conduct a new study testing the new TDS and meeting the FDA adhesion criteria as per the guidance document. This would be very difficult to achieve within 180 days. If DBV could not do this within 180 days, then it would have to withdraw the BLA.

113. CW1 further noted that DBV was a small company, and that he was "certainly not the only one" who knew about the adhesion problems. CW1 recalls having informal conversations with the Senior Director of Market Development (Food Allergies) concerning adhesion problems. CW1 stated that Defendant Benhamou, as well as the other senior executives at the Company, had to have known about the adhesion problems because by the end of the PEPITES trial the

senior executives had the trial data and the adhesion problems would not have been a "surprise."

114. CW1 elaborated on how manufacturing issues prevented DBV from fixing the Viaskin Peanut patch's adhesion problems. CW1 described the machine used to manufacture the Viaskin Peanut patch during clinical trials as a "behemoth." DBV would eventually have to move the equipment to DBV's contract manufacturer, FAREVA, the company that would commercially manufacture the patches. CW1 explained that given that DBV utilized this key piece of large equipment to manufacture the patches, DBV was unlikely to change the adhesive used in producing the patch because it would then have to use a different machine.

115. In addition, the adhesion problem was particularly troubling and carried significant implications in terms of its efficacy. CW1 stated that the patches had to be worn daily, but that if the patch fell off, the user was not supposed to replace the patch. CW1 explained that this raised the issue of how the active ingredient protein in the patch could be delivered into the patient's skin if it could not be replaced that day.

116. Confidential Witness 2 ("CW2") worked at DBV Technologies as a Senior Director, Market Development (Food Allergies) from April 2016 to February 2018. CW2 was initially based in DBV's New York office and then at its Summit, NJ office. CW2 reported to DBV's US-based head of marketing, Jerri Ann

Thatcher, who left a few months after CW2 began working at DBV. After Thatcher left the Company, CW2 began reporting to Eric Abramson, who in turn reported to the SVP of North America Commercial, Ed Jordan. Jordan in turn reported to Charles Ruban, DBV's Chief Marketing Officer. Prior to CW2's employment with DBV, CW2 previously worked at a large pharmaceutical company, Sanofi, at which CW2 had the opportunity to observe its manufacturing processes and capabilities.

117. In the course of CW2's employment for DBV, CW2 visited the Company's manufacturing facility in France several times as part of CW2's efforts to develop educational materials regarding the allergies that Viaskin was intended to treat and how DBV's products worked and addressed those ailments. During the time periods of CW2's visits to the French manufacturing facility, DBV had been in the process of preparing its manufacturing for clinical batches of the Viaskin Peanut product. CW2 observed that DBV "didn't have experienced people" in charge of CMC and manufacturing of Viaskin Peanut. CW2 also observed that DBV's manufacturing processes and capabilities were "not as established" in relation to CW2's prior experience with Sanofi.

118. CW2 further relayed CW2's understanding that the technology DBV was seeking to employ to manufacture the Viaskin Peanut had never before been used to produce a commercial grade pharmaceutical product. CW2 said that DBV's website included information about how it uses an innovative "electro-spray"

technology to spray the allergen onto the patch, but CW2 learned that there were problems scaling up and implementing the new technology.

119. Consistent with CW1's account, CW2 also reported learning of problems of the Viaskin Peanut patch failing to stay adhered to the skin during its clinical trials. CW2 reported that because of the adhesion problems, during clinical studies it was necessary to affix the patches to patients using Tegaderm, which is a medical tape. The patch's adhesion problem created somewhat of a catch-22. On the one hand, condensation from the patient's sweat was necessary for the drug allergen's absorption in the patient's system. On the other hand, this condensation caused the patch to fall off. In this way, adhesion problems created a problem with the product's efficacy. If the patch does not adhere to the skin, it cannot and will not work. CW2 stated that Viaskin Peanut's Phase 3 trials had shown "some efficacy" but the question was whether that was enough to "warrant being in the market."

120. At the time of CW2's departure from DBV in February 2018, based on CW2's knowledge of DBV's development and manufacturing of Viaskin Peanut, and CW2's concerns relating to the same, CW2 did not believe that DBV realistically would be able to submit its BLA for Viaskin to the FDA and be successful "anytime soon." Still, CW2 explained, CW2 believed that DBV was in a

race against its competitors and needed to show progress to investors by submitting the BLA in 2018.

121. Confidential Witness 3 ("CW3") worked as an outside consultant for DBV from February 2019 through May 2019. In the course of CW3's work for DBV, CW3 learned that the reason DBV withdrew its BLA for Viaskin Peanut in December 2018 was because of a quality control problem with the manufacturing system used to spray the active ingredient onto the patches. More specifically, DBV's electrospray technology could not produce the proper dose for the Viaskin Peanut patch consistently. DBV had trouble controlling the exact 250mg dose needed to be sprayed onto each Viaskin patch due to the spray-jets becoming clogged while running at full production. In other words, DBV was unable to consistently produce the Viaskin Peanut product at optimal production levels required for commercial production and FDA approval.

122. During the Class Period Defendants knew that: 1) DBV was incapable of manufacturing reproducible and consistent Viaskin Peanut patches because of problems with DBV's electrospray technology (i.e. the electrospray jets became clogged during production) and thus DBV had serious CMC and cGMP problems and 2) DBV could not produce a patch that adhered to the user's skin, and it failed to meet the FDA's prespecified adhesion criteria for the Phase III clinical trials, casting serious doubt Viaskin Peanut patch's efficacy, and making it highly unlikely

that FDA would approve a BLA. Despite Defendants' knowledge of the foregoing they continued to mislead investors about the status of the Viaskin Peanut patch's manufacturing readiness and the clinical trials' ability to successfully support a BLA.

B. During the Class Period, and Particularly Leading up to Defendants' March 2018 Public Offering, Defendants Misled Investors About the Status of Viaskin Peanut's CMC and Manufacturing Readiness

123. On February 14, 2018 the Company issued a press release entitled, "DBV Technologies Provides Update on Regulatory Progress for Viaskin Peanut," which stated the FDA agreed that the available efficacy and safety data for Viaskin Peanut supported the submission of a Biologics License Application ("BLA"). The press release stated, in relevant part:

> DBV Technologies Provides Update on Regulatory Progress for Viaskin Peanut
>
> DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT) today announced that the U.S. Food and Drug Administration (FDA) has agreed that the available efficacy and safety data for Viaskin Peanut supports the submission of a Biologics License Application (BLA) for the treatment of peanut allergy in children four to 11 years of age.
>
> The FDA provided written responses to the clinical pre-BLA meeting package submitted by the Company, which reflect agreement on the content of the clinical module of the BLA for Viaskin Peanut. ***DBV remains on track to submit its BLA in the second half of 2018.***
>
> "We are pleased with this positive step forward in our progress towards potential approval of Viaskin Peanut, and appreciate the feedback we received from the FDA supporting submission of our BLA," said Dr.

> Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. "There are approximately one million children in the U.S. diagnosed with this life-threatening disease, and we look forward to continue working with the agency to address this urgent unmet medical need."

124. The foregoing statement was false and misleading because DBV was not "on track" to submit its BLA at the end of 2018 because, as Defendants were aware, the Company suffered from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls necessary to support a BLA for FDA approval or to support a commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the Phase III clinical trials. This put the patch's effectiveness in serious doubt and made it highly unlikely FDA would approve a BLA.

125. The market responded exuberantly to DBV's long-awaited announcement that the FDA viewed the Viaskin patch's safety and efficacy data as supporting a BLA and had agreed to the clinical module of the BLA for the Viaskin Peanut, bringing DBV one step closer to FDA approval of the Viaskin Peanut for sales in the U.S. After DBV's February 14, 2018 announcement the price of DBV's

ADS increased $5.64 per share, a 27% increase from the prior day's closing price. DBV ADS also traded at a whopping *nineteen times* the previous day's volume.

126. Analysts likewise responded by upgrading DBV. For example, on February 14, 2018 JMP Securities LLC ranked DBV "market outperform" setting a price target for DBV of $30.00 (compared to the then-current trading price of $20.86).

127. On February 22, 2018, DBV's Chief Operating Officer boasted of the Viaskin Peanut's CMC readiness and DBV's manufacturing capabilities at the Royal Bank of Canada Healthcare Conference stating, in part:

> *Let's talk about CMC and manufacturing a little bit for a minute. It's also important to understand that DBV Technologies is a company that praises itself for having developed an end-to-end process and a supply chain. So if you take the example, the Viaskin Peanut, we've been able to develop from the peanut itself up to the patch, the final product, all the different processes, manufacturing processes and the new scale developed in order to be able to support the launch of our drug in the U.S. and in other territories.*
>
> So what does it mean? Basically, we've developed the manufacturing of an API. The API is a purified, localized extract of peanut developed in our labs and transferred to a CMO that is actually FDA approved. *And we also have developed, which is super specific to DBV, a technology to actually produce these patches.* It's called Electrospray and those machines have been developed by our engineers and have been transferred it to another CMO. ***So we've been able to actually bring everything up to speed in order to scale up*** *our activities and to supply the markets once the product will be, hopefully, launched in 2019.*
>
> If you actually have the chance to travel to France in the couple of months and if you have to visit the DBV offices, you'll be amazed to

> see that there are a lot of scientists doing research in our company *but also a lot of engineers really making this into a product*…
>
> *We also have developed not only the patch, but also the way to manufacture this patch and the technology that you see here on the left-hand side of the slide is called Electrospray.* So basically, we spray the protein or the peptide that we need on through an electric field of 20,000 volts through a very specific process, that actually, I don't know of any kind of process in the pharma industry today. It's a very, very unique to our patch and to the way we manufacture it. This is actually the reason why we have a very nice balance within DBV research and also development.
>
> ***We are really ready in—we're getting ready on the CMC side***. We had a positive interaction with the FDA that helps us contemplate with the filing of our drug by the end of the year, and we are ready to launch that drug.

128. The foregoing statement was false and misleading because DBV was not "ready to launch" Viaskin Peanut, and the Company had not "been able to actually bring everything up to speed" for manufacturing Viaskin Peanut. To the contrary, Defendants were aware the Company suffered from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion

criteria for the Phase III trials. This put the patch's effectiveness in serious doubt and made it highly unlikely the FDA would approve a BLA.

129. On February 23, 2018, DBV published a slide deck in connection with the RBC Capital healthcare conference representing that it had a "Fully scalable, ***launch-ready manufacturing capabilities in place for Viaskin Peanut***…key commercial roles recruited and onboarded in Summit, New Jersey office."

130. The foregoing statement was false and misleading because DBV's manufacturing capabilities for Viaskin Peanut, in fact, were not "launch-ready." To the contrary, Defendants knew that DBV lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the Phase III clinical trials. This put the patch's efficacy in serious doubt and made it highly unlikely the FDA would approve a BLA.

131. In its 2017 20-F, filed on March 16, 2018, DBV described the manufacturing technology for the Viaskin patch, misleadingly representing that it was in compliance with cGMP requirements, stating: "We have engineered a proprietary manufacturing technology for Viaskin patch, which is designed to comply with the most stringent pharmaceutical production standards, including

those promulgated by the FDA, in order to enable Viaskin to deliver proteins via intact skin. This novel pharmaceutical process, which was fully developed by us, uses an electrospray to spray homogeneous, thin, dry protein layers onto the Viaskin patch…We believe this patentable technology is highly scalable and complies with cGMP requirements."

132. The foregoing statement was false and misleading because DBV's manufacturing process, in fact, was not "fully developed" and was not then in compliance with cGMP requirements. To the contrary, Defendants knew that DBV lacked adequate manufacturing procedures and quality controls to support a BLA or to support a commercial launch for FDA approval of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This adhesion failure put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

133. At a March 14, 2018 Barclay's Global Healthcare Conference DBV's Chief Business Officer Susanna Mesa boasted of the Company's in-house electrospray machine and the Viaskin Peanut's "heavy technological components," assuring investors that from a CMC standpoint, DBV was on track in terms of receiving clinical approval. Mesa stated:

> Yeah. So just as you know, we announced recently that we had our pre-BLA meeting with the FDA in which we aligned with the agency in

> terms of the content and the format for our filings for Viaskin Peanut. The content itself is being worked on right now, *so we do have our clinical team working through the clinical modules that will be submitted with the file. But we also, as you know, are a very unique product. It's a very unique product because it's a unique immunotherapy, but it also has a very heavy technological components to it, right?* It's an electrostatic patch. *We have our own machine in-house that we've developed in order to not only formulate the antigen that goes in to the patch, but you spray it in a very unique manner, which is what allows Viaskin to deliver the antigen in the skin and not through the bloodstream.*
>
> So we also have, *aside from the clinical standpoint, some CMC requirements that need to be filed with the BLA filing as well.* ***So all of those items will be ready in the second half this year, and that keeps us on track in terms of when we expect to get clinical approval*** and if the product is approved and when we would launch if the product is indeed approved.

134. The foregoing statement was false and misleading because the CMC items were not "on track" for purposes of maintaining BLA and, ultimately, clinical approval timing. To the contrary, Defendants knew the Company suffered from serious CMC shortcomings and DBV lacked adequate manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This adhesion failure put in serious doubt

the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

C. DBV Conducts a Public Offering in March 2018, Selling its Shares at Prices Artificially Inflated by DBV's False and Misleading Statements Concerning its BLA

135. On March 23, 2018, shortly after issuing false and misleading statements assuring investors that from a CMC standpoint, DBV was on track to submit a BLA, receive FDA approval and initiate commercial launch of the Viaskin Peanut, thereby inflating the price of DBV's ADS, the Company announced the closing of its underwritten offering (the "March 2018 Offering").

136. In connection with the Offering, DBV sold an aggregate of 3,527,752 ordinary shares in (i) a public offering of 1,392,015 ordinary shares in the form of 2,784,030 ADS, in the United States, Canada and certain other countries outside Europe at a public offering price of $21.26 per ADS (on the basis of an exchange rate of $1.2246=€1.00) and (ii) a concurrent private placement of 2,135,737 ordinary shares in Europe (including France) at a public offering price of €34.71 per ordinary share.

137. In addition, the Company announced that the underwriters for the global offering exercised in full their option to purchase an additional (i) 320,360 ordinary shares and (ii) 417,604 ADSs, on the same terms and conditions, bringing

the anticipated total gross proceeds from the global offering to approximately *$172.5 million*.

D. After Raising $172.5 Million From Investors, Defendants Continued to Misleadingly Assure Investors that DBV was on Track to File the BLA and Launch Viaskin Peanut

138. On June 13, 2018, at the Goldman Sachs Global Healthcare Conference, DBV acknowledged the importance of the manufacturing process, assuring investors that DBV was prepared to launch the Viaskin Peanut in 2019 based on its work "scaling up" and "refin[ing] our manufacturing process." Chief Business Officer Susanna Mesa stated:

> As I mentioned at the beginning, we have a technology that we've developed in-house, is engineering heavy and what we've done over the last year is actually prepared to be able to launch our product in 2019, Viaskin Peanut. So we've been doing a lot of work scaling up our GMP manufacturing process. *We actually refined our manufacturing process by integrating an API, the electrospray, which is the machine that's created to manufacture the patch, and what we have at the end is a commercial ready patch called Viaskin Peanut as of today. We do have one machine that's been transferred to our CMO and that will be the commercial operation machine, and we do have plans to start another machine post launch of Viaskin Peanut in 2019*.
>
> ***
>
> Most importantly, we have our electrospray machines, which are highly modular and allows us to build a broad platform. *And at the core of the innovation of the electrospray machines, we have a unique engineering capabilities that allow us to really develop this patches or this treatment with a lot of those flexibility, with high replicability, with homogenous repartition of the API's, making it very easy for us to make those very*

scalable in a commercial setting.

139. The foregoing statements were false and misleading because Defendants touted their technologies underlying the manufacturing process needed for approval of the BLA, but omitted material information that those manufacturing processes were not fully developed and reliable or commercially scalable and producible. In fact, Defendants knew DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support approval of a BLA or to support commercial launch for Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

140. Then, on September 13, 2018 at the Morgan Stanley Global Healthcare Conference, DBV responded to specific questions related to CMC readiness, pointedly—and misleadingly—assuring investors that DBV had appropriate quantities to launch the Viaskin Peanut and that the Company was well-positioned for filing a BLA from a CMC perspective:

> Q: But maybe just remind us on manufacturing, where you are with that. How many doses can you produce? How much of the market you think you can supply at launch and any sort of CMC issues, FDA inspection issues, et cetera, that we should consider.
>
> Trapp: Yeah. So, I'll start and Susanna can augment. So, I've actually

got- had a chance to go over to France and see the manufacturing process. It's really, really cool and innovative. You spray 250 micrograms into a patch with an electrostatic process. So, it gets on the patch. *And so, a very elegant process, one we've spent a lot of time continuing to perfect and scale up. We do have appropriate quantities for launch available with where we are today. The capacity of each machine is about 30 million patches. So, we believe that's enough to get us through launch and we're continuing to look at other plans for if we need a second machine, how we bring that on.* Maybe I'll ask Susanna to comment on any BLA or other.

Mesa: Yeah. I think the major hurdles from a CMC standpoint which was really the technology transfer for our commercial CMO.[6] We transferred machine back in April 2017 on time where it allowed us to finalize a technology transfer that we need get done before launch. So, I think from that standpoint, we feel pretty comfortable where we are. There was a key component that I think for us it was very important and it was making sure the FDA was going to be okay with our filing strategy. *We will be filing with two stability batches of about six months and one stability batch of three months, and they were comfortable with that approach and we confirm that in our CMC pre-BLA meetings. So, I think, overall, all of those key challenges that were important for DBV, we've tackled on. We have a really great CMC team and I think they've done a really nice job of positioning us for success as we are*

[6] A contract manufacturing organization (CMO), sometimes called a contract development and manufacturing organization (CDMO), is a company that serves other companies in the pharmaceutical industry on a contract basis to provide comprehensive services from drug development through drug manufacturing. This allows major pharmaceutical companies to outsource those aspects of the business, which can help with scalability or can allow the major company to focus on drug discovery and drug marketing instead. Services offered by CMOs include, but are not limited to: pre-formulation, formulation development, stability studies, method development, pre-clinical and Phase I clinical trial materials, late-stage clinical trial materials, formal stability, scale-up, registration batches and commercial production. CMOs are contract manufacturers, but they can also be more than that because of the development aspect. Their customers are not only expecting competitive pricing but also regulatory compliance, flexibility on the production capability and on time delivery. Overall it is required that CMO complies with good manufacturing practice from their client and official organization such as Food and Drug Administration.
https://en.wikipedia.org/wiki/Contract_manufacturing_organization

approaching filing.

141. The foregoing statement was false and misleading because Defendants touted their technologies underlying the manufacturing process needed for approval of the BLA, but omitted material information that those manufacturing processes were not fully developed, and did not meet FDA requirements and were unreliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

142. As the time for DBV to submit its BLA drew closer, DBV continued to tout its manufacturing process, assuring investors that it was able to comply with CMC by ensuring product consistency. At the October 2, 2018 Cantor Global Healthcare Conference an analyst asked:

> Q: And then from a manufacturing perspective, obviously, you've had this on pre-BLA meeting with the FDA. What did they ask for from a manufacturing standpoint? *And if you would give us some of the history of how you manufacture these patches and what give you confidence*

that you're giving- every patch is the exact same patch?

Susanna Mesa responded:

Yeah. So, that's actually been one of the uniqueness of DBV and one that we don't talk too much about is manufacturing. And the reason that's an exciting area for us is because we actually develop our own machine. They're the electrospray machines designed by actually another one of our co-founders, Bertrand Dupont, who wanted to find a way to ensure dose replicability and dose stability over time in patches. And so we came out with this new technology that's been used in the semiconductor space before, it's called the electrospray. And basically what it does is it takes on liquid formulation of an antigen. In the case of peanut, a peanut antigen is sprays to dry [indiscernible] of the patch. *And because it's highly technicalized, then it's actually pretty replicable. And we can choose in terms of how many patches we want to produce because each electrospray is just one knuckle. And as long as you can control one knuckle, you can control the other knuckle.*

So we've worked on that technology for 15 years. We're currently in our GEN4.0 machine, which is in our CMO today and [ph] for REVA in France. And from a manufacturing standpoint, the requirements of the FDA has asked are pretty much along the same line of what they've asked for their patch development. Some adhesion testing, some stability testing.

So the FDA did request three batches with stability data from the different patches *And today, one of the things that we've agreed on, on the FDA and it was one of the major, I would say, components of the file was actually the stability data*. And two of them are actually going to be at six months and then one of them at three months. It is usually customary that the three of them are all at six months, but it's something that we agreed with on the FDA during our pre-BLA meeting and we agreed to that three-month and two six-month batches.

So from the manufacturing standpoint, I think we're there. Obviously, one of the key focus for DBV and one of the important things that we have to focus on and continue hiring talent is manufacturing, right, to ensure that there's everything that we need to do by the time we launch the product is done and to make sure that we're inception ready, that

> we're working with the FDA to help them understand the electrospray to making sure that we have all of our I's dotted and our t's crossed that that at we're heading in to the approval process, *this is something that can be highly automatized and it's something that we can show the FDA that hopefully we have everything under control here.*

143. The foregoing statement was false and misleading because Defendants assured investors that "*from the manufacturing standpoint*" DBV was on track with its BLA and assured investors "we're there," when Defendants knew that its manufacturing processes and quality controls did not meet FDA requirements. Defendants omitted material information that its manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion

criteria for the clinical trials. This put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

E. DBV Technologies Announces Submission of Biologics License Application for Viaskin Peanut to the U.S. Food and Drug Administration

144. On October 22, 2018, DBV announced it had submitted a BLA to the FDA for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. DBV's press release stated, in relevant part:

> DBV Technologies (Euronext: DB - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT) today announced the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. Viaskin Peanut is the Company's lead product candidate, which is based on epicutaneous immunotherapy (EPIT), a proprietary technology platform that delivers biologically active compounds to the immune system through the skin.
>
> "This submission represents a significant step forward for those families living with peanut allergy. We are thankful for the patients, investigators and DBV employees' efforts in making this milestone possible," said Dr. Pierre-Henri Benhamou, Chairman & Chief Executive Officer of DBV Technologies. "We have been developing Viaskin Peanut for over 10 years, with over 1,000 patients studied in our clinical trials, and we are excited about the possibility of helping patients suffering from peanut allergy."
>
> Viaskin Peanut previously received Breakthrough and Fast Track Designation from the FDA in 2015 and 2012, respectively. The BLA for Viaskin Peanut is supported by a global development program comprised of seven clinical trials. Data from Phase III studies, PEPITES and REALISE, which studied patients four to 11 years of age for 12 months, as well as supportive long-term data from the

> Company's open-label Phase II program, were included in this submission.
>
> Dr. Hugh Sampson, Chief Scientific Officer of DBV Technologies and Kurt Hirschhorn Professor of Pediatrics at the Icahn School of Medicine at Mount Sinai said, "We believe that the safety and efficacy data generated in our clinical trials support our mission to potentially offer EPIT, a proprietary desensitization treatment, to peanut-allergic children in an easy and convenient manner for families."

145. It was misleading for the Company to announce the submission of the BLA and optimistic sentiment for FDA approval when Defendants were aware that DBV's manufacturing processes and quality control were inadequate to support FDA approval. Defendants misleadingly omitted material information that its manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support approval of a BLA or commercial launch for Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

F. DBV Suddenly Withdraws its BLA, Causing the Price of DBV ADS to Plummet

146. On December 19, 2018, after the close of trading, the Company issued a press release announcing that its "BLA [for Viaskin Peanut was] withdrawn

following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls[.]" The press release stated, in relevant part:

> DBV Technologies Provides Update on Viaskin Peanut for Children Four to 11 Years of Age
>
> BLA withdrawn following discussions with FDA regarding insufficient data on manufacturing procedures and quality controls
>
> DBV to work with the agency to pursue resubmission as quickly as possible
>
> The FDA did not cite concerns related to the safety or efficacy of Viaskin Peanut in the BLA
>
> *DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT) today announced that after discussions with the U.S. Food and Drug Administration (FDA), its Biologics License Application (BLA) for Viaskin Peanut in children four to 11 years of age has been voluntarily withdrawn.* DBV is currently working closely with the agency to resubmit the application for Viaskin Peanut as quickly as possible.
>
> This action was based on verbal and written correspondence with the FDA on December 18th, 2018. *Following feedback from the agency, DBV Technologies concluded that the current BLA, which was submitted on October 18th, 2018, lacks sufficient detail regarding data on manufacturing procedures and quality controls.* The FDA did not cite concerns related to the clinical module of the BLA for Viaskin Peanut, and the Company believes that the additional information needed to support this filing is available without further clinical studies.
>
> *"Although the agency did not reference any medical or clinical questions with the submission of Viaskin Peanut, the FDA did communicate that the level of detail with regards to data on manufacturing and quality controls was insufficient in the BLA,"* said Daniel Tassé, Chief Executive Officer of DBV Technologies. "We remain confident in the clinical profile of Viaskin Peanut and its potential to offer treatment to peanut-allergic children. Our plan is to

> address these concerns as quickly as possible and to work closely with the FDA to provide an updated and complete file."

147. On this news, shares of DBV Technologies fell $8.39 per share or nearly 60% to close at $5.76 per share on December 20, 2018, damaging investors.

148. DBV's bad news was good news for its rival, Aimmune Therapeutics, Inc., whose share price rose $3.76 per share on December 20, or 15% from its December 19 closing price, trading at 4.75 times its December 19 volume.[7]

149. Also on December 19, 2018, DBV hosted a conference call discussing its withdrawal of its BLA for Viaskin Peanut. The call was hosted by Daniel Tassé, DBV's new CEO. On November 16, 2018, just one month before announcing its decision to withdraw the BLA for the Viaskin Peanut, DBV announced that effective November 29, 2018 Defendant Benhamou would no longer serve as CEO and that Daniel Tassé would take over as CEO as of that date.

150. Tassé fielded analysts' questions about the CMC issues and FDA feedback that led DBV to suddenly withdraw the BLA. Tassé explained:

> These are CMC issues that often happen in this process and I've seen that before. I obviously wish to spend a lot of time to understand them fully, we've had our first read from the team already on the nature of them. And I want to make sure I come back to all of you with a clear view of what will be the time required to address them. But these seem to be questions that can be addressed. In due time, I'd be happy to come

[7] On September 13, 2019 an FDA Advisory Committee endorsed the effectiveness of Aimmune's peanut allergy treatment, known as AR101 and voted to endorse a safety plan the FDA proposed to support the treatment's use in children and teenagers.

> back and provide that clarity. But at this point in time, we need some latitude to go and understand it fully, and come back with the clarity that our patients deserve and the marketplace deserves.
>
> As far as your question, a bit more color on the comments from the FDA. They are, as we described in the press release, complements of information, precision on data, precision on analyses, SOPs, things that are again quite common as part of the BLA CMC process. And questions, again, we're very grateful for the FDA yesterday taking the time to reach out to us, have a dialogue, give us a heads up to it, so that we can assess where we are and very constructively make the decision that we've announced today.
>
> The review came at the end of the 60-day process and on the phone was the representation from all of the FDA. *The questions they had for us and be able to reach to us was all to do with CMC*. So, there was no questions, no comments made about Section 2 or about the safety, efficacy and the clinical profile of the product.
>
> . . .

151. Analysts pressed on whether the CMC issues had to do with specific formulation issues related to the Viaskin Peanut patch, to which Tassé evaded response—citing his freshman status at the Company:

> JASON ERON ZEMANSKY [of Barclays]: Just to follow up on a number of comments. ***Is the CMC questions, were they specific to the formulation that, that of patch aspect to it?*** And then, kind of to follow up, given the FDA's previous review, what should we think about in terms of the resubmission? Is there any possibility that FDA will kind of bypass some of the scientific and clinical efficacy questions to focus more on the CMC issues? Or is it going to be a complete and total review of the entire package.
>
> TASSE: Yes. I don't wish to speculate on how the FDA will approval the review here. We would expect this being, obviously, Breakthrough

> Therapy where the clinical profile is important that the FDA will be reviewing, obviously, the whole file.
> . . .
>
> And again, I want to be very clear. I want – I'm new.

152. Analysts drilled down on the timing of when Defendants learned of the FDA's concerns with the BLA:

> TAZEEN AHMAD [of BOFA Merrill Lynch]: …can you give us a sense of when discussions with the FDA regarding specifically manufacturing started, because obviously with the breakthrough status that would mean that the company would have had multiple opportunities, I think, to communicate with the agency either in writing or in person or on the phone. Was this something that was brought up recently in your discussions or can you just give us a timeline of when this popped up?
>
> TASSE: Yeah. The FDA reached out to us on Monday to say- I'm sorry, on Tuesday, yesterday- to say that we have a number of observations we'd like to share with you. They were again, as I say, very constructive in doing it and giving us heads up, a chance to think through how we want to handle it. We chose to withdraw the file, so that we can address those concerns of theirs in a way that it- we've all the latitude to do it obviously and do it the right way, both those discussions actually emerged in the last day.
>
> AHMAD: In terms of what other options they gave you besides the option to withdraw, can you give us some color on that?
>
> TASSE: Yeah. The other option was to continue with the file, quite simply, but the right decision here was for us to withdraw the file. With the feedback that was provided by the agency, again, it was very constructive, so that we have great clarity on the questions the agency wants us to address. And with that great clarity and that collegial approach, we chose to pull the file, to withdraw it, and carefully and

precisely asses the best way to respond to those questions here.

AHMAD: …[D]o you think that this will be simply addressing the questions about manufacturing and moving on as planned with the BLA?

TASSE: Well, you're asking me to speculate on what the agency will do once we resubmit here. *We do know that what they've asked to discuss with us and what they express has been the areas they want us to focus on, all had to do with CMC and manufacturing*.

153. In response to whether the Company was in a position to arrange a formal meeting with the FDA, Tassé suggested that the Company first needed to marshal additional resources and hire FDA experts in order to address the CMC issues:

TASSE: We will bring in outside expertise, people who are experts in these areas and also have worked with the FDA in the past, so that we can decide whether or not a dialogue with the agency is indicated as part of our response here. That's something I believe the agency would be very much amenable to do, but that decision has not been made at this point in time.

JOSEPH PATRICK SCHWARTZ [of Leerink]: …So, I think you said that you believe the information that you need to support the filing is available without further clinical studies, but then you also want to take some time to understand it as well and you can to address it with great precision. So, I'm just wondering how strongly do you think that you understand what the FDA has issues with and how strongly do you think you can address the FDA's issues without having to do, for example, additional manufacturing campaigns? Have you been capturing the types of information on the product and how it's produced in terms of specs and things in order to address the issues that the FDA is raising now?

TASSE: Yeah. The dataset, the data capture we have I think is one that

> I need to query and understand fully here. We have to be honest with each and other in a situation right now that was, obviously, not one that we were expecting here.
>
> SCHWARTZ: …Did the FDA say that you would receive a RTF if you did not withdraw the application? I'm just wondering why this can't be resolved in the normal course of the review and if this implies that it will take more time than that, the withdrawal of the BLA?
>
> TASSE: Yeah. The withdrawal of the BLA allows us to do all of this in a time that we control and that struck me as maybe the best option.

154. When asked when the Company became aware of the CMC deficiencies in the BLA for the Viaskin Peanut, Tassé deflected, emphasizing that he had only worked at the Company for three weeks:

> LIISA ANN BAYKO [of JMP]: *Did you have any sense before that the application was deficient on any of these components*? ….
>
> TASSE: *Any sense from the agency? No.*
>
> BAYKO: No, *Just on your own, kind of, review*.
>
> TASSE: *I've been here for three weeks*…I'm still very much in the diligence mode….So I wish I could give you a more complete answer.

155. Tassé confirmed that the FDA's feedback, and DBV's decision to withdraw the BLA, related to not only one particular deficiency but "many elements of CMC:"

> MATTHEW KELSEY HARRISON [of Morgan Stanley]: . . .can you just maybe comment on the scope of the questions, did it cover broadly all areas of CMC or was it focused on a certain area, say, documentation

> or release assay validation or something like that?
>
> TASSE: Yeah, *so it touches many elements of CMC*, but all the observations were rather precise. So, these were very, very specific observations that did not go to all of systems, *but it went to specific observations, specific questions the agency had around our processes here*. So, they were not, what I would say, comments on the overall system or overall SOPs, but quite precise questions here that again are – what I've seen in my experience, exactly the type of questions that you'd get from the agency in a review here…..precise questions that touch many elements of our manufacturing process.

156. Tassé further responded to analysts' questions concerning how DBV produced the product in a cGMP manner and doubled-down on the Company's ability to reproduce consistent dosages of Viaskin Peanut:

> SCHWARTZ: So obviously, you don't have any approved products, which are coming out of your manufacturing facilities and then electrospray technologies is advanced -- impressive, ***but can you tell us how you've designed this in order to produce product in [cGMP] manner? I'm just wondering about things like the consistency of dosage that's on each patch***, shelf stability at different temperatures and things like that. I mean, have you had an opportunity to think about the basic list of things that you would expect the FDA would want to scrutinize like dosing and stability. Anything else...

In response, Defendant Tassé reassured investors as to the state of manufacturing:

> TASSE: So I've spent a good chunk of last week for the manufacturing people in Bagneux. And I have said, I was quite impressed by the technology, the cleverness of it. ***And I'm comfortable -- very comfortable that our ability to, essentially, manufacturing the patch and deliver 250 micrograms with great consistency from one patch to the other is something that the team has very much achieved***.
> . . .
> ***But I -- the core technology, the ability to make a patch is something that I think is very solid and our ability to do that in a way that is***

consistent is something that I was impressed when I saw the facility in Bagneux last week.

157. Tassé's statements concerning DBV's sudden withdrawal of the BLA for the Viaskin Peanut were false and misleading because Defendants had known throughout the Class Period that DBV's manufacturing processes actually were not fully developed and reliable. In fact, DBV suffered from serious CMC shortcomings and lacked sufficient manufacturing procedures and quality controls to support a BLA for FDA approval or to support commercial launch of Viaskin Peanut. In addition, and relatedly, DBV was unable to produce a patch that sufficiently adhered to the patient's skin, failing the FDA's prespecified adhesion criteria for the clinical trials. This put in serious doubt the patch's effectiveness and made it highly unlikely the FDA would approve a BLA.

G. DBV Announces Plans to Resubmit the BLA for Viaskin Peanut to the FDA

158. On February 13, 2019 the Company issued a press release announcing plans to resubmit its BLA application for Viaskin Peanut patch in the third quarter of 2019. The press release stated:

> DBV Technologies Provides Update on Regulatory Status of Viaskin Peanut for the Treatment of Peanut Allergic Children 4 to 11 Years of Age Progress made to date to enable BLA resubmission in Q3 2019 Company to hold conference call today, February 13th, at 4:30 ET / 22:30 CET DBV Technologies (Euronext: DBV – ISIN: FR0010417345 – Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today

> announced that its planned resubmission of the Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for Viaskin Peanut in the treatment of peanut allergic children 4 to 11 years of age is anticipated in the third quarter of 2019
>
> "We appreciate the detailed feedback the FDA provided in December 2018, which has allowed us to make meaningful headway in addressing the information requests needed for a BLA resubmission," said Daniel Tassé, Chief Executive Officer of DBV Technologies. "We are working diligently on our Viaskin Peanut BLA, bringing us one step closer to potentially providing an FDA-approved treatment for peanut-allergic children and their families."

159. The same day, the Company held an investor "Viaskin Peanut Update Call," during which Defendant Tasse and DBV's new head of Manufacturing and Operations, Julie O'Neill fielded questions from analysts. On the call Tassé reassured investors that DBV had undertaken a comprehensive review of not only CMC issues but the entire BLA for resubmission:

> LISA BAYKO: ***Can you describe what if any other tweaks you're going to make to the BLA resubmission outside of the CMC module***?
>
> TASSE: That's a good question. ***As I mentioned, we're going to use the opportunity since we have to invest time in answering the CMC questions, also, take a look at the whole- the clinical trial***. As I said, there have been no indication whatsoever from the agency that there are any questions about the clinical dossier. ***But we're just giving it a once-over to be certain here that there's nothing else that we may***

want to round off or to add to it. <u>At this point in time, nothing has been identified.</u> But out of principle, we have a look at it.

160. The foregoing statement was false and misleading because DBV had in fact identified issues with patch-site adhesion even prior to submitting the BLA in 2018 that adversely affected not only CMC but efficacy. Defendants were aware that DBV lacked adequate manufacturing procedures and quality controls to remedy the adhesion issues which impacted the Viaskin Peanut's efficacy such that the product could not successfully support a BLA for FDA approval.

161. When Defendants announced that DBV would be resubmitting its BLA shares of DBV ADS rose 11% in after-hours trading.

H. Defendants Publish Full Results from the PEPITES Study in JAMA, Deceitfully Omitting that the Viaskin Peanut patch Failed

to Meet the FDA's Prespecified Adhesion Criteria and Misleadingly Redefining Adhesion

162. On February 22, 2019 the full results of the PEPITES Study were published in the Journal of American Medicine ("JAMA").

163. As noted herein, Defendants were aware of the FDA's prespecified adhesion criteria, a requirement for FDA approval of Viaskin Peanut, by no later than October 4, 2017.

164. Dr. Lavin, in reviewing the PEPITES Study in JAMA, noted that the Study fails to state whether or not the results met the FDA's prespecified adhesion criteria.

165. Defendants did not reveal the true adhesion data in the PEPITES study or elsewhere precisely because they knew it failed the FDA's prespecified adhesion criteria and wanted to conceal this adverse news from investors.

H. DBV Conducts a Public Offering in April 2019, Selling its Shares at Prices Artificially Inflated by DBV's False and Misleading Statements Concerning its BLA

166. On April 8, 2019, shortly after issuing false and misleading statements assuring investors that from a CMC as well as a clinical standpoint, DBV was on

track in terms of submitting the BLA and receiving clinical approval which artificially inflated the price of DBV's ADS, the Company announced the closing of its underwritten offering (the "April 2019 Offering"). In connection with the April 2019 Offering, DBV sold an aggregate of 6,000,000 ordinary shares in (i) an offering of 2,447,500 ordinary shares in the form of 4,895,000 ADS, in the United States, Canada and certain other countries outside Europe at an offering price of $6.75 per ADS (on the basis of an exchange rate of $1.1233=€1.00) and (ii) a concurrent private placement of 3,552,500 ordinary shares in Europe (including France) at a public offering price of €12.02 per ordinary share.

167. In addition, the Company announced that the underwriters for the global offering exercised in full their option to purchase an additional (i) 782,608 ordinary shares and (ii) 1,565,216 ADSs, on the same terms and conditions, bringing the anticipated total gross proceeds from the global offering to approximately *$81 million*.

I. After Raising $81 Million From Investors, Defendants Continued to Misleadingly Assure Investors that DBV was Back on Track to File the BLA and Launch Viaskin Peanut

168. On May 14, 2019, at the Bank of America Merrill Lynch Health Care Conference, DBV assured investors that it had privileged access to the FDA because

of Viaskin Peanut's breakthrough status, and that DVB could and would talk to the FDA not only about CMC but the entire "clinical package:"

> Q: So Daniel, maybe you can talk about where you are in terms of your discussions with the FDA about your application and time lines for responding. And you did talk about that in the fall- excuse me earlier this year about what type of information FDA would want in order to get the application back on track.
>
> TASSE: …When the process of responding and generating all the data necessary to answer those question from the agency, we've communicated in February that we plan to refile in the third quarter of this year, that very much remains the plan.
>
> AHMAD: And so based on your conversation with the agency, your Breakthrough status gives you opportunities to have increased communication with the folks at FDA. And I guess since this update, can you give us a general idea of the types of interactions you've been having with them and, to the extent that you can, talk about the area of focus of those interactions.
>
> TASSE : Correct. We've had no need to go and talk to the agency about the CMC file because for those of you that are knowledgeable at pharmaceutical manufacturing, the nature of the observations of the FDA were very clear, unmistakably clear. So there was no ambiguity, what were the deficiencies were clearly explained. What we needed to do to respond to them was something that was straightforward for us to conceptualize and get the work done. ***That being said, the fact that we do have this privileged access to the agency under our Breakthrough designation is something we plan on making use of as we get closer to having closure on the CMC filing to go talk to the agency, not only about the CMC file but also about the clinical package and try to see what is reasonable when it comes to review time and making the product available to our patients.***

169. The foregoing statements were false and misleading because Defendants touted the fact that they had gotten all the work done in remedying the

deficiencies the FDA had communicated. Defendants omitted material information that the Viaskin Peanut patch also had patch-site adhesion problems that cast serious doubt on the patch's efficacy and that indeed, the patch failed to meet the FDA's required prespecified adhesion criteria for the clinical trials. As a result of the adhesion failure, the FDA was highly unlikely to approve a BLA.

170. Then, on June 12, 2019, at the Goldman Sachs Global Health Care Conference, Defendant Tassé misleadingly assured investors that there were no problems with the clinical profile of the Viaskin Peanut:

> Tassé: And I think it's important to revisit the fact that the FDA focused specifically on manufacturing, but they can confirm that there were no clinical or safety issues. *They were not, the regulations are clear that at this point in the process, of course was the end of the 60 day review, the agency would have owed us all of their critical observations, cannot reserve it only to CMC.* That added to the fact that as we've discussed that the condition from the agency in the minutes, their response to a meeting went back until 2018, makes it quite clear that the clinical dose here is a very much viable. So our view remains unchanged.

171. The foregoing statement was false and misleading because Defendants touted the fact that the FDA had not found any clinical or safety issues with the Viaskin Peanut but omitted material information that DBV could not manufacture a patch that sufficiently adhered to the patient's skin and had failed to meet the FDA's prespecified adhesion criteria for the clinical trials. This put the patch's

efficacy in serious doubt and made it highly unlikely the FDA would approve a BLA.

172. At the Goldman Sachs Healthcare conference Defendant Tassé additionally assured investors that the Viaskin Peanut was on the cusp of regulatory approval and ready for commercialization:

> Q: So, as you are a company that's kind of on the cusp of a potential regulatory approval, commercialization is next up. And I assume the Company is, as it's focused on remediating the BLA, is also getting ready for commercialization.
>
> TASSE: Yes, we are.

173. The foregoing statement was false and misleading because DBV was not on the cusp of regulatory approval. In fact, DBV could not manufacture a patch that sufficiently adhered to the patient's skin and failed to meet the FDA's prespecified adhesion criteria for the clinical trials. This put in serious doubt the

Viaskin Peanut patch's efficacy and made it highly unlikely the FDA would approve a BLA.

J. DBV Technologies Announces Resubmission of Biologics License Application for Viaskin Peanut to the U.S. Food and Drug Administration

174. On August 7, 2019, DBV announced it had resubmitted a BLA to the FDA for Viaskin Peanut for the treatment of peanut allergy in children four to 11 years of age. DBV's press release stated, in relevant part:

> The submission addresses the additional data needed on manufacturing procedures and quality controls which were communicated by the FDA in December 2018, when DBV voluntarily withdrew its prior BLA submission for Viaskin Peanut. The FDA did not cite concerns related to the clinical module of the BLA for Viaskin Peanut in December 2018.

175. The foregoing statement was false and misleading because the submission did not disclose the fact that the Viaskin Peanut patch failed to meet the FDA's prespecified adhesion criteria, which Defendants had been aware of since February 2019, at the latest. Further, Defendants were aware of patch-site adhesion problems even before DBV submitted its BLA in 2018. DBV could not manufacture a patch that sufficiently adhered to the patient's skin, and it failed to meet the FDA's

pre-specified adhesion requirement for the clinical trials. This put in serious doubt the patch's efficacy and made it highly unlikely the FDA would approve a BLA.

176. Analysts responded to Defendants' announcement that DBV had resubmitted the BLA for the Viaskin Peanut patch to the FDA with vigorous enthusiasm, upgrading DBV ADS. For example, on August 8, 2018 JP Morgan issued a price target of $20 and rated DBV ADS Market Outperform stating.

> DBVT resubmitted its BLA for Viaskin Peanut after the company voluntarily withdrew the original application in December to address concerns the FDA had regarding manufacturing procedures and quality controls. ***We are pleased that management's steps to correct these deficiencies have ensured that the program is back on track after this setback. Moreover, the FDA did not cite any issues related to the clinical module of the initial BLA. We anticipate that potential acceptance of the BLA later this year could be pivotal for DBVT as Viaskin could be the first drug approved for peanut allergy in children 4-11 years of age.***
>
> ***We view the potential acceptance of the BLA by year-end as a major de-risking event for DBVT shares, as we project a 60% likelihood of approval for the program, which we view to be a several billion-dollar market opportunity.***

177. Then, on October 4, 2019 DBV announced the FDA accepted the BLA for Viaskin Peanut for review and set a target action date of August 5, 2020.[8] DBV's press release stated, in relevant part:

> DBV Technologies, (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has accepted for review the Biologics License Application (BLA) for its investigational Viaskin® Peanut immunotherapy for the treatment of peanut-allergic children ages 4 to 11 years.
>
> "The acceptance of the Viaskin Peanut BLA is a meaningful step forward for peanut-allergic patients and their families," stated Daniel Tassé, Chief Executive Officer of DBV Technologies. "We commend the tireless efforts of the DBV team, the investigators and the more than 1,000 patients living with peanut allergies who participated in our clinical trials and made this milestone possible. We know children and their families are seeking a safe and effective treatment that may fit into their daily lives. We look forward to continuing to work with the FDA to potentially bring Viaskin Peanut to patients in the second half of 2020."

178. It was misleading for the Company to announce the acceptance of the BLA and optimistic sentiment for FDA approval when Defendants were aware that DBV could not manufacture a patch that adhered to patient's skin and it failed to meet the FDA's prespecified adhesion criteria for the Phase III clinical trials. This

[8] A FDA Action date tells when an FDA regulatory action, such as an original or supplemental approval, took place. https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms

cast serious doubt on Viaskin Peanut patch's efficacy, and made it highly unlikely that FDA would approve a BLA. Despite Defendants' knowledge of the foregoing they continued to mislead investors about the status of the Viaskin Peanut patch's manufacturing readiness and the clinical trials' ability to support a successful BLA

K. DBV Conducts a Public Offering in October 2019, Selling its Shares at Prices Artificially Inflated by DBV's False and Misleading Statements Concerning its BLA

179. On October 15, 2019, shortly after issuing false and misleading statements assuring investors that DBV had remedied all issues with the Viaskin Peanut patch standing in the way of FDA approval and imminent commercialization which artificially inflated the price of DBV's ADS, the Company announced the closing of its underwritten offering (the "October 2019 Offering"). In connection with the October 2019 Offering DBV sold an aggregate of 9,484,066 ordinary shares in (i) an offering of 7,914,622 ordinary shares in the form of 15,829,244 ADS, in the United States, Canada and certain other countries outside Europe at an offering price of $6.59 per ADS (on the basis of an exchange rate of $1.0945=€1.00) and (ii) a concurrent private placement of 1,569,444 ordinary shares in Europe (including France) at a public offering price of €12.04 per ordinary share.

180. In addition, the Company announced that the underwriters for the offering exercised in full their option to purchase an additional (i) 1,368,667 ordinary shares and (ii) 2,737,334 ADSs, on the same terms and conditions,

bringing the anticipated total gross proceeds from the global offering to approximately $143 million.

After Raising $150 Million From Investors, Defendants Continue to Misleadingly Assure Investors that DBV was on Track to Launch Viaskin Peanut, and Raise Another $153.7 Million From Investors in Yet Another Public Offering, Selling More Shares at Prices Artificially Inflated by DBV's False and Misleading Statements

181. On January 8, 2020 DBV issued a press release reporting positive three-year long-term data from the PEOPLE Phase III Open-Label Extension Study of Viaskin Peanut in Children with Peanut Allergy. The press release stated in part:

> Harnessing the important immune properties of the skin, epicutaneous immunotherapy represents a potentially unique mechanism of action that may support the sustained desensitization observed in this study even after a period without treatment. *These data further advance our understanding of the profile of Viaskin Peanut, which is currently under review by the U.S. Food and Drug Administration and may offer a simple, once daily, non-invasive treatment option for children living with peanut allergy in the second half of 2020, if approved*," said Dr. Pharis Mohideen, Chief Medical Officer of DBV Technologies.

182. The foregoing statement was false and misleading because Defendants touted the profile of the Viaskin Peanut patch and the potential for FDA approval in the second half of 2020, but omitted material information that DBV could not manufacture a patch which sufficiently adhered to the patient's skin, that the patch failed to meet the FDA's prespecified adhesion criteria for the clinical trials and that

as a result the patch's efficacy was in serious doubt and that FDA was highly unlikely to approve a BLA.

183. Then, on February 4, 2020 DBV announced that it had closed yet another public offering, (the "February 2020 Offering") this time raising an additional $153.7 million, making the total amount DBV raised from investors in Class Period share offerings to a whopping $532.2 million.

184. In connection with the February 2020 Offering, DBV sold an aggregate of 7,500,000 ordinary shares in (i) an offering of 4,535,581 ordinary shares in the form of 9,071,162 ADS, in the United States, Canada and certain other countries outside Europe at an offering price of $10.25 per ADS (on the basis of an exchange rate of $1.0999=€1.00) and (ii) a concurrent offering exclusively addressed to qualified investors in Europe (including France) of 2,964,419 at a public offering price of €18.63 per ordinary share.

185. In addition, the Company announced that it had granted the underwriters a 30-day overallotment option allowing them to purchase up to 1,125,000 ordinary shares in the form of 2,250,000 ADS, bringing the anticipated total gross proceeds from the global offering to approximately $153.7 million.

L. Defendants Announce a May 15, 2020 FDA Advisory Committee Meeting, Continuing to Assure Investors that Nothing Stood in the Way of FDA Approval of the Viaskin Peanut Patch

186. On February 21, 2020 DBV issued a press release announcing an FDA advisory committee meeting to review Viaskin Peanut for the treatment of peanut allergy in children. The press release stated, in relevant part:

> DBV Technologies (Euronext: DBV - ISIN: FR0010417345 - Nasdaq Stock Market: DBVT), a clinical-stage biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) has announced an Allergenic Products Advisory Committee meeting to be held on May 15, 2020 to discuss the Biologics License Application (BLA) for Viaskin™ Peanut. Viaskin Peanut, which is based on epicutaneous immunotherapy (EPIT), is an investigational drug currently under review by the FDA as a treatment for peanut allergy in children.
>
> "There remains a significant unmet need for children suffering from peanut allergy, a potentially life-threatening condition," Daniel Tassé, Chief Executive Officer of DBV Technologies stated. "We welcome the opportunity to present data for the first and only epicutaneous immunotherapy and remain steadfast in our commitment to offer this important new treatment option to patients and their families in the second half of 2020, if approved."

187. It was misleading for the Company to announce an FDA meeting to discuss the BLA and make optimistic statements about FDA approval when Defendants were aware that DBV could not produce a patch that sufficiently adhered to the patient's skin to support FDA approval**,** causing the patch to fail to meet the FDA's prespecified adhesion criteria putting the patch's efficacy in serious

doubt. Defendants misleadingly omitted material information that because DBV could not manufacture a patch that sufficiently adhered the patient's skin this undermined the patch's efficacy. In fact, Defendants were aware that the patch could not adhere to the patient's skin since the beginning of the Class Period and were additionally aware that they could not fix this problem. This made it highly unlikely the FDA would approve a BLA.

188. Then, on February 26, 2020 at the 9th Annual SVB Leerik Global Healthcare Conference DBV assured investors that DBV had rectified all outstanding issues with Viaskin Peanut and that nothing stood in the way of FDA approval. On the call Defendant Tasse stated:

> We were first faced with the setback of a delay that we had to pull and re-file. All that work was done. The team did a fantastic job. We refiled in early August. The file was accepted for review on October 4th giving us an action date from the FDA for a potential hopeful approval of our product, Viaskin Peanut to treat the peanut allergies in children between the age of 4 and 11 on August 5th this year. So that obviously is the big event that will be the fruit of many, many years of work by the scientific founders of the company. And then, just we're proud to be stewards of all the good work.

189. The foregoing statement was false and misleading because Defendants assured investors that Defendants did all the "work" necessary to remedy the deficiencies that required the Company to pull the BLA in December 2018, when Defendants knew that because DBV still could not manufacture a patch that sufficiently adhered to the patient's skin and in fact failed to meet the FDA's

prespecified adhesion requirement that were clearly set forth in the SAP, the Viaskin Peanut patch did not meet FDA requirements for approval. In fact, the adhesion issues with the Viaskin Peanut patch had existed since prior to December 2018 and Defendants still lacked the ability to consistently manufacture a patch that could adhere to the patient's skin. This made it highly unlikely the FDA would approve a BLA.

M. DBV Announces the FDA Has Efficacy Concerns Which May Require a "Major Amendment" to the BLA, Causing the Price of DBV ADS to Plunge 52%

190. On March 16, 2020, DBV issued a press release disclosing that "the U.S. Food and Drug Administration (FDA) has informed the Company that during its ongoing review of the Biologics License Application (BLA) for investigational Viaskin™ Peanut, it has identified questions regarding efficacy, including the impact of patch-site adhesion." DBV further advised investors that it "is in communication with the FDA regarding the potential submission of additional information on patch-site adhesion from its clinical program as well as long-term efficacy results from the three-year open-label extension study, PEOPLE, to answer FDA's questions" and that while the Company "has received no additional information regarding the timeline of the BLA review . . . *the submission of*

additional information to the FDA may constitute a major amendment to the BLA and could extend the target action date."

191. On this news, shares of DBV Technologies fell $2.72 per from a closing price of $5.26 per share on March 16, 2020, to open at $2.54 on March 17, 2020—a one-day drop of nearly 52%, damaging investors.

192. Also on March 16, 2020, DBV hosted a conference call addressing the Company's announcement that the FDA had identified "new questions regarding efficacy including the impact of patch-site adhesion on efficacy" and that accordingly, the FDA cancelled the May 15, 2020 APAC meeting with DBV to discuss the BLA. On the call Tassé stated:

> Today, we issued a press release announcing that FDA has informed us that during its ongoing review of the BLA for investigational Viaskin Peanut, it has identified new questions regarding efficacy, including the impact of patch-site adhesion on efficacy. As a result, the Allergenic Products Advisory Committee meeting, or APAC, to discuss our BLA will no longer take place as scheduled on May 15, 2020.
>
> Importantly, during the pre-BLA meeting and subsequent discussions, the FDA did not raise any concerns regarding efficacy related to patch adhesion. So this is a new development in our ongoing dialogue that we will work to address.
>
> At this time, we have received no additional information regarding the timeline of the BLA review, and to the company's knowledge, the target action date of August 5, 2020 remains unchanged at this time. *However, any*

additional information that we provide to the FDA may constitute a major amendment to the BLA and could extend the target action date."

193. On the call Tassé fielded questions from analysts. Responding to a question seeking "more specifics around efficacy questions raised by the FDA," Tassé stated:

> ***The questions from the agency have to do with the potential impact on efficacy of patch adhesion and patch attachment. Again, that's something we have looked at closely since we have the products, we very much believe that patch adhesion is not a factor in clinical outcome and are looking forward to engaging with the agency on discussing exactly that.***
>
> LIISA ANN BAYKO: Can you—I guess I don't understand what we're talking about here. What is patch site adhesion related to efficacy? What is the specific question the FDA has?
>
> TASSE: Yes, let me—that's—let me summarize for you what has been sort of the dimensions of this year. So there was a 90% adhesion rate. So adhesion means the patch is scored 0, 1, 2, 3, 4. So 0 or 1 means the patch has stayed on or just the corner sort of was lifting up a bit; 2 or 3 means the patch was lifting or falling off. ***So the adhesion rate that was prespecified by the FDA based on their transdermal patch experience was that 90% adhesion rate was required. The adhesion rate in PEPTITES was below the prespecified 90% from both placebo and active arms.*** Now the mean duration of application times for patches of incomplete adhesion was within a protocol prespecification of 24 plus-or-minus 4 hours for both placebo and active arm. We also know that the main reason for adhesion issues was scratching, what the kids would—did essentially to address what was the pruritus and skin irritation that has been well documented with the product here. And then we did a subgroup analysis that showed that similar clinical benefits in subjects reporting patch adhesion issues, subjects with no

> more than 10% patches that were 2 or 3 compared to the general study population suggested no substantial impact on clinical efficacy.
>
> ***
>
> ***It's the intersection of adhesion and efficacy is what we've heard in our conversation with the agency today.***

194. Tassé's statements concerning the FDA's concerns about patch-site adhesion were false and misleading, because whether or not the FDA previously raised the issue of patch-site adhesion, Defendants had known throughout the Class Period that DBV could not manufacture a patch that consistently and sufficiently adhered to the patient's skin. Further, Defendants knew no later than the date they published top-line results of the PEPITES study on October 20, 2017, that the patch failed to meet the FDA's prespecified adhesion criteria clearly set forth in the SAP. Indeed, as Tassé admitted, the FDA *prespecified* that DBV was required to demonstrate a 90% adhesion rate for BLA approval of the Viaskin Peanut patch, and that the adhesion rate in the PEPITES study was below that rate.

195. As Dr. Lavin explains, it is highly unlikely that the FDA would waive the criteria set forth in a SAP, meaning that if the trial data a manufacturer like DBV submits to the FDA in support of the BLA does not meet the requirements set forth in the SAP, the FDA is highly unlikely to approve the product. Accordingly, because Defendants were aware of the results of the PEPITES study and were aware

that the patch failed to meet the FDA's prespecified adhesion criteria, Defendants knew that it was highly unlikely that the FDA would approve the BLA.

VI. ADDITIONAL ALLEGATIONS REGARDING DEFENDANTS' SCIENTER

196. During the Class Period, DBV had no approved drugs and generated no significant income from operating activities. The Company had spent 10 years developing Viaskin Peanut, DBV's lead product candidate and had just recently before the Class Period completed a Phase 3 study that demonstrated efficacy. Viaskin Peanut was far ahead of DBV's other prospective products in terms of clinical development and was thus a critical product candidate and the focus of significant attention by the Company. By Defendants' own admissions, the CMC for Viaskin Peanut and developing and maintaining manufacturing processes that were cGMP compliant was an important focus of the Company during the Class Period, supporting a strong inference of scienter.

197. The suspicious timing of DBV's announcement of its withdrawal of the BLA in December 2018 also supports a strong inference of scienter. As explained above, from the time a marketing application is submitted, the FDA has 60 days to perform an initial review. During this time FDA will determine if the submission is sufficiently complete to accept the application for filing and thereafter perform a more substantive review. Because the purpose of this initial 60-day

review period is to allow the FDA to identify and communicate application deficiencies to the applicant, and to allow the applicant to cure them, the FDA typically communicates such problems to an applicant as early during the review period as possible. This supports a strong inference that Defendants were aware of the CMC problems identified by the FDA prior to announcing the BLA withdrawal on December 19, 2018—a mere two days before the FDA's filing decision was due.

198. Defendant Tassé's admission that the FDA prespecified that the Viaskin Peanut patch had to demonstrate a 90% adhesion rate also supports an inference of scienter. As explained above, Defendants had the results of the PEPITES study no later than the date they announced the top-line results, on October 20, 2017, and knew from the study results that the Viaskin Peanut patch did not meet the FDA's required adhesion criteria as set forth in the SAP dated October 2017. Knowing that Viaskin Peanut had failed to meet the FDA's pre-specified adhesion rate in its Phase III trials, Defendants knew it was highly unlikely the FDA would approve the BLA.

199. The suspicious timing of the resignation of DBV's CEO, Pierre-Henri Benhamou, during the Class Period further supports scienter. On November 29, 2018, just over a month after the BLA was submitted and just three weeks before

DBV's announcement that it was withdrawing the BLA for the Viaskin Peanut, DBV co-founder Pierre-Henri Benhamou stepped down as CEO.

200. Then, on January 3, 2019, two weeks after DBV withdrew its BLA, DBV announced that that its Chief Medical Officer Dr. Lucia Septien-Velez was leaving the Company to "pursue other opportunities." Hugh Sampson would assume the role of CMO.

201. Furthermore, on March 5, 2019, DBV announced that Pierre-Henri Benhamou had resigned from the Board of Directors. On November 29, 2018, Benhamou stepped down from his post as CEO, but remained on the Board of Directors until March 5, 2019. Again, the Company's press release stated that "Dr. Benhamou did not express any disagreement with the Company on any matter relating to the Company's operations, policies or practices," but provided no reason for his departure. Also on March 5, 2019 DBV announced that Charles Ruban, the Company's Chief Operating Officer who oversees regulatory, product development and commercial operations would be leaving the Company to "pursue new

opportunities." And DBV also announced that Laurent Martin, Chief Development Officer would leave his regulatory and product development role.

202. Finally, on May 14, 2019, DBV announced that Defendant Schilansky had stepped down as deputy CEO. DBV stated that Schilansky has decided to leave the Company to "pursue other professional opportunities."

VII. CORPORATE SCIENTER

165. During the Class Period, Defendants Tassé, Benhamou, Schilansky and Mesa served as CEO and CFO, Principal Financial Officer and CBO, respectively. As CEO and CFO, Tassé, Benhamou and Schilansky signed Class Period SEC filings on behalf of DBV. Defendant Tassé signed DBV's 2018 20-F filed with the SEC on April 1, 2019. Defendant Benhamou signed the Company's 2017 20-F filed with the SEC on March 16, 2018. Defendant Schilansky signed the Company's 2017 20-F and 2018 20-F filed with the SEC on March 16, 2018 and April 1, 2019, respectively. Defendants Tassé, Benhamou and Schilansky therefore, acted with apparent authority to speak on behalf of the Company and their statements were made with the imprimatur of the Company that selected them to speak on its behalf. Moreover, as CEO, CFO, Principal Financial Officer and Chief Business Officer, Defendants were highly involved in the preparation, review, finalization, and

issuance of the Company's statements, and investors relied on their honesty and integrity.

166. Based on the foregoing, Defendant Tassé's, Benhamou's, Schilansky's and Mesa's actions and scienter are imputable to DBV at all times during the Class Period. Defendants Tassé, Benhamou, Schilansky and Mesa acted as an agent of DBV, both with respect to the SEC filings that they signed and also with respect to the SEC filings, press releases and conference calls that they assisted in preparing and/or that they oversaw or participated in. Therefore, Defendants Tassé's, Benhamou's, Schilansky's and Mesa's state of mind is imputable to DBV for all of

the challenged statements in this Complaint, whether or not they personally signed those statements.

VIII. APPLICABILITY OF PRESUMPTION OF RELIANCE

A. Fraud-on-the-Market Doctrine

203. Investors are entitled to rely, and will rely, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. the omissions and misrepresentations were material;

c. DBV ADS are traded in an efficient market;

d. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of DBV's ADS; and

e. Investors and members of the Class purchased, acquired and/or sold DBV ADS between the time the Defendants failed to disclose or misrepresented material facts and the time the true

facts were disclosed, without knowledge of the omitted or misrepresented facts.

204. At all relevant times, the market for DBV ADS was an efficient market for the following reasons, among others:

- DBV's ADS met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

- During the Class Period, the average weekly trading volume for DBV ADS on the NASDAQ was 894,217 shares, which represents approximately 1.52% of DBV's outstanding ADS during the Class Period permitting a strong presumption of reliance;

- At least 9 stock market analysts followed DBV and wrote a total of at least 44 reports on DBV during the Class Period. Analysts covering DBV included: Stifel Nicolaus; SVB Leerink; Barclays; Jefferies; JMP Securities LLC; Morgan Stanley; Kempen & Co; H.C. Wainwright & Co. and; Deutsche Bank;

- DBV regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures,

such as communications with the financial press and other similar reporting services;

- More than 25 member firms were active market-makers in DBV ADS at all times during the Class Period;
- During the Class Period DBV was eligible for S-3 registration;
- DBV's market capitalization exceeded $840 million on all days during the Class Period.
- Unexpected material news about DBV was rapidly reflected and incorporated into the Company's stock price during the Class Period.

205. As a result of the foregoing, the market for DBV promptly digested current information regarding DBV from all publicly available sources and reflected such information in DBV's stock price. Under these circumstances, all purchasers of DBV ADS during the Class Period suffered similar injury through their purchase of DBV ADS at artificially inflated prices, and a presumption of reliance applies.

B. Affiliated Ute

206. Neither Investors nor the Class need prove reliance – either individually or as a class – because under the circumstances of this case, positive proof of reliance is not a prerequisite to recovery, pursuant to ruling of the United States Supreme Court in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972). All that is necessary is that the facts withheld be material in the sense

that a reasonable investor might have considered the omitted information important in deciding whether to buy or sell the subject security.

IX. INVESTORS' CLASS ACTION ALLEGATIONS

207. Investors bring this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired DBV Technologies ADS traded on NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of DBV Technologies, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

208. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, DBV Technologies ADS were actively traded on the NASDAQ. While the exact number of Class members is unknown to Investors at this time and can be ascertained only through appropriate

discovery, Investors believe that there are hundreds, if not thousands of members in the proposed Class.

209. Investors' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

210. Investors will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Investors have no interests antagonistic to or in conflict with those of the Class.

211. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the financial condition and business DBV Technologies;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the

statements made, in light of the circumstances under which they were made, not misleading;

- whether Defendants caused DBV Technologies to issue false and misleading SEC filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false and SEC filing
- whether the prices of DBV Technologies' securities during the Class Period were artificially inflated because of Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

212. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it

impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

X. CLAIMS FOR RELIEF

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder Against All Defendants

213. Investors repeat and reallege each and every allegation contained above as if fully set forth herein.

214. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

215. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order

to make the statements made, in light of the circumstances under which they were made, not misleading.

216. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of DBV Technologies securities during the Class Period.

217. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of DBV Technologies were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of DBV

Technologies, their control over, and/or receipt and/or modification of DBV Technologies' allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning DBV Technologies, participated in the fraudulent scheme alleged herein.

218. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Investors and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other DBV Technologies personnel to members of the investing public, including Plaintiff and the Class.

219. As a result of the foregoing, the market price of DBV Technologies securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Investors and the other members of the Class relied on the statements described above and/or the integrity of the market price of DBV Technologies securities during the Class Period in purchasing DBV Technologies

securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

220. Had Investors and the other members of the Class been aware that the market price of DBV Technologies securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased DBV Technologies securities at the artificially inflated prices that they did, or at all.

221. As a result of the wrongful conduct alleged herein, Investors and other members of the Class have suffered damages in an amount to be established at trial.

222. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of DBV Technologies securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

223. Investors repeat and reallege each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

224. During the Class Period, the Individual Defendants participated in the operation and management of DBV Technologies, and conducted and participated,

directly and indirectly, in the conduct of DBV Technologies' business affairs. Because of their senior positions, they knew the adverse non-public information about DBV Technologies' misstatement of revenue and profit and false financial statements.

225. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to DBV Technologies' financial condition and results of operations, and to correct promptly any public statements issued by DBV Technologies which had become materially false or misleading.

226. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which DBV Technologies disseminated in the marketplace during the Class Period concerning DBV Technologies' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause DBV Technologies to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of DBV Technologies within the meaning of Section 20(a) of the

Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of DBV Technologies securities.

227. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by DBV Technologies.

XI. PRAYER FOR RELIEF

WHEREFORE, Investors, on behalf of themselves and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiffs as Lead Plaintiffs and certifying Plaintiffs as class representatives under Rule 23 of

the Federal Rules of Civil Procedure and designating Plaintiffs' counsel as Lead Counsel;

(b) awarding damages in favor of Investors and the other Class members against all defendants, jointly and severally, together with interest thereon;

(c) awarding Investors and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding Investors and other members of the Class such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.

Dated: June 12, 2020

Respectfully submitted,

THE ROSEN LAW FIRM, P.A.

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Email: kwolke@glancylaw.com

Co-Lead Counsel for Lead Plaintiffs and the Putative Class

CERTIFICATION

The individual or institution listed below (the "Plaintiff") authorizes the Rosen Law Firm, P.A. to file an action or amend a current action under the federal securities laws to recover damages and to seek other relief against DBV Technologies S.A. (NASDAQ: DBV) and its current and former officers and directors. The Rosen Law Firm, P.A. agrees to prosecute the action on a contingent fee basis not to exceed one-third of any recovery and will advance all costs and expenses. Any legal fees and expenses will be determined by, and payable, only upon order of the U.S. District Court.

Plaintiff declares, as to the claims asserted under the federal securities laws, that:

1. I have reviewed the complaint against DBV and its current and former officers and directors and I retain the Rosen Law Firm, P.A. as counsel in this action for all purposes.

2. I did not engage in transactions in the securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in this or any other litigation under the securities laws of the United States.

3. I am willing to serve as a lead plaintiff either individually or as part of a group. A lead plaintiff is a representative party who acts on behalf of other class members in directing the action, and whose duties may include testifying at deposition and trial.

4. The following is a list of all of the purchases and sales I have made in DBV securities during the Class Period set forth in the complaint. I have made no transactions during the Class Period in the securities that are the subject of this lawsuit except those set forth below.

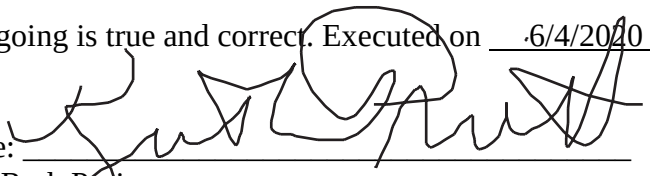
Number of Shares Purchased or Sold	Date(s) Purchased	Price Paid Per Share	Date(s) Sold (if applicable)	Price Sold Per Share
1,000	10/23/2017	$23.85		$
900	4/5/2018	$23.85		$
100	4/5/2018	$23.83		$
1,000	7/19/2018	$17.45		$
1,000	11/14/2018	$16.25		$
456	1/23/2019	$5.80		$
2000	3/16/2020	$2.24	3/18/2020	$2.79
		$		$
		$		$
		$		$
		$		$
		$		$
		$		$
		$		$
		$		$

PLEASE FAX CERTIFICATION TO ROSEN LAW FIRM at (212) 202-3827
OR MAIL OR EMAIL:
THE ROSEN LAW FIRM PA
275 Madison Avenue, 40th Floor
New York, New York 10016
info@rosenlegal.com

5. I have not, within the three years preceding the date of this certification, sought to serve or served as a representative party on behalf of a class in an action involving alleged violations of the federal securities laws, except: for the following company(ies):

6. I will not accept any payment for serving as a representative party beyond my pro rata share of any recovery, except reasonable costs and expenses, such as travel expenses and lost wages directly related to the class representation, as ordered or approved by the court pursuant to law.

I declare under penalty of perjury that the foregoing is true and correct. Executed on 6/4/2020.

Signature: 

Name: Ruth Pruitt

Address: [redacted]

Phone: [redacted]

E-mail: [redacted]

Item. 4 (continue from prior page if needed)

Number of Shares Purchased or Sold	Date(s) Purchased	Price Paid Per Share	Date(s) Sold (if applicable)	Price Sold Per Share
		$		$
		$		$
		$		$
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		$		$
		$		$

SWORN CERTIFICATION OF PLAINTIFF

DBV TECHNOLOGIES S.A. SECURITIES LITIGATION

I, Asdrubal Delgado, certify that:

1. I have reviewed the Complaint and authorize its filing and/or the filing of a Lead Plaintiff motion on my behalf.

2. I did not purchase the DBV Technologies S.A. securities that are the subject of this action at the direction of plaintiff's counsel or in order to participate in any private action arising under this title.

3. I am willing to serve as a representative party on behalf of a class and will testify at deposition and trial, if necessary.

4. My transactions in DBV Technologies S.A.securities during the Class Period set forth in the Complaint are as follows:

   (See attached transactions)

5. I have not sought to serve, nor served, as a representative party on behalf of a class under this title during the last three years, except for the following:

6. I will not accept any payment for serving as a representative party, except to receive my pro rata share of any recovery or as ordered or approved by the court, including the award to a representative plaintiff of reasonable costs and expenses (including lost wages) directly relating to the representation of the class.

I declare under penalty of perjury that the foregoing are true and correct statements.

5/30/2020
Date

DocuSigned by:
Asdrubal Delgado
A53384162F4B43F...
Asdrubal Delgado

Asdrubal E. Delgado's Transactions in DBV Technologies S.A. (DBVT)

Date	Transaction Type	Quantity	Unit Price
6/15/2018	Bought	2,000	$20.5035
12/21/2018	Bought	150	$5.1963
12/21/2018	Bought	150	$5.1963

Exhibit 1

Name: **PHILIP T. LAVIN**

Industry Experience:

Summary: 45 years in clinical trials serving as an expert biostatistician, regulatory strategist, and executive

2013 – Present	Principal Lavin Consulting LLC
1988 – Present	Founder and Executive Director Boston Biostatistics Research Foundation Inc.
2019 – Present	Founder Melior Capital Management

Current responsibilities include:

Senior biostatistics (strategic planning, study design, endpoint construction, modeling, analysis, and representation), regulatory strategy (agency interaction and presentation), helping sponsors secure approval for drugs, biologics, and devices and reimbursement leading to 71 regulatory approvals and clearances (40 PMAs/CE Marks, 20 NDAs, 4 BLAs, 1 HDE, and 6 510k clearances) and one GRAS petition.

2011 – 2013	Executive Vice President, Strategic Planning and Innovation Center Aptiv Solutions
2007 – 2011	Executive Chairman and Vice Chairman of the Board Averion International
1983 – 2007	Founder and CEO Averion International (formerly Boston Biostatistics Inc.)
1983 – 2015	Special Government Employee FDA

Past responsibilities included:

Executive management, strategic management, regulatory strategy, biostatistics, talks, publications, and collaborations in pre-clinical studies, clinical trials, and innovative approaches for study design, longitudinal modeling, meta and mega analyses, epidemiology, cost-benefit modeling, and health care reimbursement, while serving as an FDA advisor and panel member for drugs, devices, and biologics.

Academic Experience:

1989 – 2005	Adjunct Associate Professor, Clinical Associate Professor Harvard Medical School, Boston, MA 02115
1983 – 1989	Associate Professor Harvard School of Public Health Boston, MA 02115
1977 - 1983	Assistant Professor Harvard School of Public Health Boston, MA 02115

1974 - 1977	Research Assistant Professor, Statistical Laboratory, Statistical Science Division, SUNY at Buffalo, Buffalo NY
1972 – 1974	Assistant Professor of Research, Division of Applied Mathematics, Brown University, Providence RI

Responsibilities included:

Teaching, research, cooperative group (ECOG, GITSG) collaborations, and publications

Education:

Brown University, Providence RI
PhD, Applied Mathematics (Statistics), 1972

University of Rochester, Rochester NY (Summa Cum Laude)
AB, Mathematics, 1968

Patents:

System and Method for Diagnostic Vector Classification Support (to differentiate between benign and malignant breast masses based on three internal and two external features using statistical algorithms); Patent # 9,398,893 issued July 26, 2016

System and Method for Diagnostic Vector Classification Support; Patent # 10,026,170 issued July 17, 2018

Presentations:

2016	AHA Frontiers in Stem Cells Research: Statistical Considerations FDA Industry Workshop: Writing Statistical Contracts
2015	SOCRA: The Statistics Behind Risk Based Monitoring MDIC: Optimizing Medical Device Study Designs FDA Industry Workshop: Statistical IP Considerations SABCS: Breast Cancer Detection Algorithms
2014	SABCS: Nomogram for Breast Cancer Diagnosis RAPS: Adaptive Designs for Regulatory Submissions
2013	AIUM: Opto-acoustics for Breast Cancer Detection RAPS: Maximizing Good Relationships with Regulatory Agencies
2012	Q1 Productions: Planning and Executing Adaptive Designs Q1 Productions: Statistical Strategies for Medical Device Studies
2011	Q1 Productions: Statistical Strategies for Medical Device Studies IBC: Reimbursement Planning Strategies using Phase 3 Data
2010	IBC: Adaptive Designs for Biologics and Drugs
2009	IBC: Statistical Designs for Biomarkers
2008	JSM: Quasi-non-inferiority Designs for Medical Devices

2007	Mass BioTech Council: "Statistical Challenges Supporting DMCs" Neonatology Summit: "Mortality and LOS Modeling Issues Comparing Surfactants" American Statistical Association: "Designing Quasi-superior Device Studies"
2006	American Statistical Association: "Common Themes in Medical Device Studies"

FDA/EMA Approvals and Clearance/Clinical Trials Experience:

Drugs
(20 NDA approvals):
Acid Reflux (Axid)
Acne (Estrostep, Azelex)
AIDS (Foscavir)
Anemia (Fereheme)
ARDS
Asthma (Albuterol)
Cystic Fibrosis (ZenPep)
Cushing Syndrome
Diabetes
Endometriosis
Epilepsy
Frederich's Ataxia
Gastric Ulcers
Glaucoma
Hepatology
Hyperlipids (Cholestagel)
Hyperkalemia (Lokelma)
Hypertension
Infection (Ceftobiprole)
Lipidemia (Lipitor)
Macular Edema
Motion Sickness (Refaximin)
Multiple Sclerosis
Obesity
Oncology (Adriamycin)
Oncology: GI (Erbitux), Lung, Brain, H&N, Ovarian
Onychomycosis
Osteo-arthritis (Flurbiprofen)
Pain Relief (EMLA)
Pulmonary: COPD
Renal (Renagel)
Rosacea (Finacea)
Substance Abuse (Naltrexone, Nalbuphine)
Suicide Prevention
Urinary Incontinence

Biologics
(4 BLA approvals):
Burns
Decubitis Ulcers
Gum Disease (GINTUIT)
Hepatitis B and C
Huntington's Disease
Liver Assist Device
Melanoma (OncoVex)
Multiple Sclerosis
Oncology (ONTAK)
Psoriasis
Renal Assist Device
Rheumatoid Arthritis
Sepsis
Transplants
Vaccines (OspA)
Wound Healing

GRAS (1 approval)
Enteral Nutrition (IMPACT)

Devices (40 PMAs/CE Marks, 1 de novo, 1 HDE approvals, 6 510k clearances):
Adhesion Prevention (ADCON-L)
Angina (TMR)
Ankle Healing (Augment)
Artificial Organs: Heart, Kidney, Liver
Biomarkers (CA-125, PSA, sIL2r)
Breast Cancer Imaging (Imagio)
Cardiac Access (Crossing Solutions)
Cardiac Adhesions (REPEL-CV)
Catheter Lock Solution (Zuragen)
Cervical Disc (Mobi-C [1,2], ProDISC-C [1,2])
Cervical Dysplasia Detection (LUNA, DysisMap)
Connective Tissue (Orthogold 100)
Cryoablation (FROSSTY)
Dermal Filler (RADIESSE)
Diabetes: Glucose Monitoring
Dialysis (Zuragen)
Diagnostics (DR [IDx])
Fat Reduction (eon FR)
Femoral Artery Closure (VCD [3])
Finger Implant (PCP)
Fracture Healing (SAFHS)
Hip Implant (C/C)
Imaging: US, CT, MRI, MGA, OA, SPECT
Knee: Cartilage repair and regeneration
Knee OA IA (OrthoVisc, Synvisc, SUPARTZ, Gel-One, Monovisc, GenVisc850, Hymovis)
Lumbar Disc (ProDISC [1,2])
Metastatic Pain Relief (Quadramet)
Neurologic Vessel Repair (LVIS, FRED)
Neurological Impulses (NC-Stat)
Ophthalmology: Glaucoma, Macular Disease
Osteoporosis Detection (SAHARA)
Periodontal Regeneration (GEM 21S)
Peripheral Crossing System (SoundBite)
Rib Spacer (VEPTR)
Sacral Implants (SI-BONE)
Screening (CRC [Cologuard])
Spinal Fusion Cage (BAK)
Ulcers: Decubitis, Venous Stasis
Wound Healing (APLIGRAF)

Research Expertise:

Clinical:	Applications:	Methodology:
Biomarkers	Multiple endpoints	Adaptive design
505(b)2	Multiple comparisons	Sequential analysis
Bioequivalence	Composite endpoints	Longitudinal modeling
Biosimilars	Artificial intelligence	Simulations
Devices	Multi-study modeling	Exact inference
Drugs	Cost-benefit modeling	Prediction
Combination Products	Optimization models	Survival analyses
Imaging	Instrument validation	Time series
Biologics	Meta analyses	Markov processes
Quality of Life	Cost reimbursement	Bayes modeling
Companion Diagnostics	Adaptive modeling	Interim analyses
Vaccines	Registries	Survey sampling
Veterinary Products	Predictive models	Epidemiology
Pharmacovigilance	Sample size models	Classification
		Missing at random

Technical Experience:

Software: MS Word, PowerPoint, Excel, StatXact, nQuery, EaSt, ADDPLAN

Honors/Awards:

2009	RAPS Fellow
2008	ASA Fellow
2007	Earl Robinson Award, The American Society of Periodontology
2007-	Who's Who in the World
2006	Earl Robinson Award, The American Society of Periodontology
2000	The American Society of Reproductive Surgery
1999 -	Who's Who in America
1985 -	Who's Who in International Medicine
1984 -	Who's Who in Cancer Research
1981 -	Who's Who in Technology Today
1976 -	Who's Who in American Men of Science
1968 - 1972	National Science Foundation (NSF) Fellowship
1968	Phi Beta Kappa

Public Service:

1987 – 1993	NASCO, Continuing Education
1986 – 1997	Statistical Editor, Antimicrobial Agents and Chemotherapy
1986 – 1989	Editorial Board, Drug Information Association (DIA)
1983 - 2015	FDA Special Government Employee
1981 – 1999	NIH Grants and Contracts Reviewer

Affiliations/Memberships:

2013-	American Society of Nephrology
2012-	World Molecular Imaging Society
1986-	Regulatory Affairs Professional Society

1984- Drug Information Association
1979- Biometrics Society
1976- American Statistical Association

Publications

ORIGINAL ARTICLES

1. Douglass HO, Jr., Lavin PT. A Study of Nitrosourea Toxicity in Gastrointestinal Protocols of the Eastern Cooperative Oncology Group, Cancer Treatment Reports, 60:769-780, 1976.

2. Schein P, Lavin P, et al for the Gastrointestinal Tumor Study Group, Randomized Phase II Clinical Trial of Adriamycin, Methotrexate, and Actinomycin D, in Advanced Measurable Pancreas Carcinoma, Cancer, 42:19-22, 1978.

3. Falkson G, Moertel C, Lavin P, for the Eastern Cooperative Oncology Group, Chemotherapy Studies in Primary Liver Cancer, A Prospective Randomized Clinical Trial, Cancer, 42:2149-2156, 1978.

4. Douglass HO, Jr., Lavin PT, et al. for the Eastern Cooperative Oncology Group, Chemotherapy of Advanced Measurable Colorectal Cancer, Cancer, 42:2538-2545, 1978.

5. Carbone PP, Davis TE, Zelen M, Lavin P, Eastern Cooperative Oncology Group - Progress Report of Activities and Plans, Cancer Clinical Trials, 1:65-75, 1978.

6. Schapira D, Hall T, Bennett J, Lavin P, Schnider B, for the Eastern Cooperative Oncology Group, A Phase II Study in Estradiol Mustard, Cancer Clinical Trials, 1:5-8, 1978.

7. Chu, TM, Lavin P, Day J, Evans J, Mittelman, A, Holyoke, E, Vincent, R, Carcino-Embryonic Antigen: Prognosis and Monitoring of Cancer, Carcino-Embryonic Proteins, Vol. I, Elsevier/North Holland Biomedical Press, 1979.

8. Lokich J, Lavin P, Moertel C, et al, for the Gastrointestinal Tumor Study Group, A Multi-Institutional Comparative Trial of Radiation Therapy Alone and in Combination with 5-Fluorouracil for Locally Unresectable Pancreatic Carcinoma, Annals of Surgery, 189:205-208, 1979.

9. Moertel CG, Engstrom P, Lavin PT, Gelber R, Carbone P, for the Eastern Cooperative Oncology Group, An Evaluation of 5-FU, Lactones, and Nitrosoureas in Patients with Advanced Non-Measurable Gastric and Pancreas Cancer, Journal of Surgery, 85:509-513, 1979.

10. Douglass HO, Lavin PT, Evans J.T, Mittelman A, Carbone PP, Phase II Evaluation of Diglycoaldehyde, VP-16-213, and the combination of Methyl-CCNU and Beta-2'-Deoxythioguanosine in Previously Treated Patients with Colorectal Cancer: An Eastern Cooperative Oncology Group Study (EST-1275), Cancer, 63:1355-1357, 1979.

11. Lavin P, Holyoke D, Zamcheck N, for the Gastrointestinal Tumor Study Group, A CEA Standardization Experiment for the Conduct of Multi-institutional Trials, Cancer Treatment Reports, 63:2031-2033, 1979

12. Moertel CG, Lavin PT, for the Eastern Cooperative Oncology Group, Phase II-III Chemotherapy Studies in Advanced Gastric Cancer, Cancer Treatment Reports, 63:1863-1869, 1979.

13. Lavin PT, and Moertel CG, for the Gastrointestinal Tumor Study Group, Phase II-III Chemotherapy Studies in Advanced Gastric Cancer, Cancer Treatment Reports, 63:1871-1876, 1979.

14. Lokich JJ, Childs DS, Kalser M.H, Lavin PT, Douglass HO, et al, for the Gastrointestinal Tumor Study Group: Comparative therapeutic trial of radiation with or without chemotherapy in pancreatic carcinoma, Int J Radiat Oncol Biol Phys 5:1643-1647, 1979.

15. Lavin PT, and Flowerdew G, Studies in Variation Associated with the Measurement of Solid Tumors, Cancer, 46:1286-1290, 1980.

16. Lavin PT, Mittelman A, Douglass H, Engstrom P, Klaassen D, Survival and Response to Chemotherapy of Colorectal Adenocarcinoma, Cancer, 46:1536-1543, 1980.

17. DeWys W, Begg C, Lavin PT, et al, for the Eastern Cooperative Oncology Group, Prognostic Effect of Weight Loss Prior to Chemotherapy in Cancer Patients, American Journal of Medicine, 69:491-497, 1980.

18. Macdonald JS, Schein PS, Woolley PV, Smythe T, Ueno W, Hoth D, Lavin P. 5-Fluorouracil, doxorubicin, and mitomycin (FAM) combination chemotherapy for advanced gastric cancer Annals Internal Medicine 93 (4), 533-536, 1980.

19. Kinsella TJ, Bloomer W.D, Lavin PT, Knapp RC, Stage II Endometrial Carcinoma: 10 Year Followup of Combined Radiation and Surgical Treatment, Gynecologic Oncology, 10:290-297, 1980.

20. Falkson G, Moertel C, MacIntyre J, Lavin P, Engstrom P, Carbone P, The Value of Cytostatic Agents in the Treatment of Patients with Primary Liver Cancer, Diagnosis and Treatment of Upper Gastrointestinal Tumors, International Congress Series No. 542, 455-459, 1980.

21. Osband M, Lipton J, Lavin P, Levey R, Vawter G, Greenberger J, McCaffrey R, Parkman R, Histiocytosis-X: Demonstration of Autoimmunity, Suppressor Cell Deficiency and Successful Treatment with Thymic Extract, New England Journal of Medicine, 304:146-153, 1981.

22. Lavin P, Day J, Holyoke ED, Mittelman A, Chu TM, An Evaluation of Baseline and Followup CEA in Patients Undergoing Resection for Cure for Colorectal Carcinoma, Cancer, 47:823-826, 1981.

23. Osband M, Shen Y, Shlesinger M, Lavin P, et al, Successful Tumor Immunotherapy with Cimetidine in Mice, Lancet, 1:636-638, 1981.

24. Wagoner M, Albert D, Lavin P, Corneal Donor Material Selection, Ophthalmology, 83:139-144, 1981.

25. Moertel C, Lavin PT, et al, for the Gastrointestinal Tumor Study Group, Therapy of Locally Unresectable Pancreatic Carcinoma: A Randomized Comparison of High Dose Radiation Along, Moderate Dose Radiation + 5-FU, and High Dose Radiation + 5-FU, Cancer, 48:1705-1710, 1981.

26. Lavin P, Alternative Measures of Anti-Tumor Activity in the Evaluation of Solid Tumors, Cancer Clinical Trials, 4:451-459, 1981.

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28. PS Schein, Gastrointestinal Tumor Study Group. A comparison of combination chemotherapy and combined modality therapy for locally advanced gastric carcinoma. Cancer 49 (9), 1771-1777.

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30. Karp DD, Ervin TJ, Tuttle S, Gorgone B, Lavin PT, Yunis E.J, Pulmonary Complications During Granulocyte Transfusions: Incidence and Clinical Features, Vox Sanguinis, 42:57-61, 1982.

31. Harmon W, Lavin P, Parkman R, Ingelfinger J, Grupe W, Levey R, The Correlation of Early Acute Rejection Episodes with Long-Term Renal Transplant Outcome, Transplantation, 33:648-649, 1982.

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33. Moertel CG, Lavin PT, Hahn G, Phase II Evaluation of Adriamycin in Islet Cell Carcinoma, Cancer Treatment Reports, 66:1567-1569, 1982.

34. Harmon W, Parkman R, Lavin P, Grupe W, Ingelfinger J, Yunis E, Levey R, Comparison of Cell Medicated Lympholysis and Mixed Lymphocyte Culture in the Immunological Evaluation for Renal Transplantation, Transplantation, 129, 4:1573-1577, 1982.

35. Lavin PT, Bruckner, H, Plaxe, S, Studies in Prognostic Factors Relating to Chemotherapy for Advanced Gastric Cancer, Cancer, 50:2016-2023, 1982.

36. Gonder JR, Shields JA, Albert DM, Augsburger JJ, Lavin PT, Uveal Malignant Melanoma Associated with Ocular and Oculodermal Melanocytosis, Ophthalmology, 89, 8:953-960, 1982.

37. Lavin PT, Structure Preserving Image Restoration, IEEE Pattern Analysis and Machine Intelligence, 5:14-24, 1983.

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39. Johnson LA, Lavin P, Moertel CG, et al, Carcinoids: The Association of Histologic Growth Pattern and Survival, Cancer, 51:882-889, 1983.

40. Bast RC, Reinherz EL, Mayer C, Lavin P, Schlossman SF, Contrasting Effects of Cyclophosphamide and Prednisolone on the Phenotype of Human Peripheral Blood Leukocytes, Clinical Immunology and Immunopathology, 28:101-114, 1983.

41. Lavin PT, Practical Considerations in the Coordination of Clinical Trials, in Issues in the Conduct of Clinical Trials, T. Louis and S. Shapiro (Eds.), Marcel Dekker, New York City, 129-153, 1983.

42. Albert D, Searl S, Lavin P, Uveal Findings in Patients with Cutaneous Melanoma, American Journal of Ophthalmology, 95:474-479, 1983.

43. Engstrom, PF, Lavin PT, Klaassen, DJ, Phase II Evaluation of Mitomycin and Cisplatin in Advanced Esophageal Carcinoma, Cancer Treatment Reports, 67, 7-8:713-715, 1983.

44. Albert DM, Searl SS, Forget B, Lavin PT, Kirkwood J, Nordlund JJ, Uveal profile in patients with cutaneous melanoma, Am J Ophthalmol. 95(4):474-479, 1983.

45. Seddon, J, Albert, D, Lavin P, A Prognostic Factor Study of Disease-Free Interval and Survival Following Enucleation for Uveal Melanoma, Archives of Ophthalmology, 101:1894-1899, 1983.

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